



Counterfeit medicines and criminal organisations

Eric Przyswa

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Study report

COUNTERFEIT MEDICINES AND CRIMINAL ORGANISATIONS

Report presented by IRACM

Author: Eric Przyswa



Eric Przyswa, Research Fellow Mines ParisTech in the Centre for Research on Risks and Crises, is the author of this report for the Institute of Research against Counterfeit Medicines (IRACM). The author writes in many French and foreign academic reviews (Hermès, Futuribles, Tribune de la santé, Information and Society, etc.) and conducts research on the human safety.

The report is available in its entirety on: www.iracm.com.



Institut de Recherche Anti-Contrefaçon de Médicaments

10 avenue Franklin Roosevelt
75008 Paris - France
info@iracm.com

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Foreword

Today, drug counterfeiting is a rapidly growing phenomenon in both developed and developing countries. The number of victims is rising, as is the income derived - almost with impunity - from transnational organized crime.

The International Institute of Research against counterfeit Medicines (IRACM) intends to devise measures to better understand the phenomenon, educate and motivate leaders, rally public opinion, warn potential victims and to facilitate the implementation of strategies related to these issues, both from governments and the international community. This is the IRACM's very reason for existing.

Drug counterfeiting is primarily a 'dark figure', and most likely a considerable one. The effectiveness and credibility of the solutions are subject to a systematic and comprehensive understanding of the phenomenon, all its aspects, its mechanisms and the strategy of organized crime, which, in many parts of world, has become a leading activity.

This is why the IRACM decided to support the creation of an in-depth study and instructed a particularly competent researcher in the field, Eric Przyswa, to conduct it.

The work he has achieved is substantial and we now know more thanks to him. He has written a very full report, which, once published, will no doubt be a milestone in the understanding of the role of organized crime in drug counterfeiting and the implications and effects of these truly transnational crimes. Transnational because they thrive in the wake of globalization by exploiting the destitution in poor countries and the credulity of the people in rich countries.

Through this report, the IRACM wishes to inform as many citizens of the world as possible of the dangers and threats it has revealed, and to ensure that policymakers take them into account to implement the necessary action, contain organized crime, protect society and safeguard the rule of law in our countries against the power these criminals have gained.

Bernard Leroy, Director of IRACM



Introduction

The combat against counterfeiting started during the 1980s and, at that time, was limited to sectors where it was frequently the consumer who asked for the product, and was even party to the purchase. Above all, it is only since the start of the 2000s that the situation expanded substantially particularly with the liberalisation of the WTO¹, technological developments, containerisation and the significance of China as the world's factory. On the other hand, it was only later that counterfeiting seemed to affect the pharmaceutical sector, at least from the industrial point of view. Studies and reports have covered the involvement of organised crime in 'traditional' counterfeiting, particularly in creative industries (luxury goods, audiovisual).

Nevertheless, even if there are more and more discussions on the topics of 'counterfeit medicines' and 'organised crime', very few researchers have analysed the relationship between the two phenomena.

Consequently, it appeared that such a report should be written and a dual objective was decided:

- To take as objective and as rigorous a view as possible on the reality of the "counterfeiting – criminal organisations" combination in the area of medicines.
- From a criminology and strategic standpoint, to give some consideration to what could be done to guide current actions.

What about the reality of this phenomenon? How can criminal organisations be characterised in our area of study? Are these organisations transnational? Is the Internet a genuine Eldorado for criminal organisations dealing in medicines?

The questions relating to our problems proved to be varied and complex. One of the interests in this research is to offer new food for thought on a potentially real, but still opaque threat for which an interpretation can only be made through a documented, pragmatic and also imaginative approach.

In the first part, the framework of our new conceptual study will be explained. It is important to define the counterfeiting and falsification of medicines in a clear field of analysis, presenting the specific features of the Internet in particular.

In the second part, we will analyse the reality of the relationship between counterfeit medicines and criminal organisations both in the physical world and on the Internet. Theoretical considerations will also supplement our own thoughts.

Thirdly, we will go into detail on the criminological issues raised by our problems. Finally, we will analyse to what extent knowledge of the phenomenon can be improved and therefore eliminated with new forms of expertise.

¹ World Trade Organization.

I. Medicine counterfeiting, criminal organisations and cybercrime

I.1. Counterfeiting, falsification and medicines

It is essential to better determine the concepts relating to our problems so that the current challenges may be painstakingly identified.

The issue in counterfeit medicines is an old one since Dioscoride (born towards 40 A.D.), a Greek doctor and botanist, already gave advice on how to detect fake medicines². More recently³, in post-war Vienna, counterfeit penicillin was detected in 1948, an event used in the famous film noir *The Third Man*, directed by Carol Reed.

Etymologically, the origin of the term *counterfeiting*⁴ comes from the 18th century Latin word *contrafacere* which means 'imitate' and, generally speaking, counterfeiting is therefore a fraudulent reproduction intended to mislead the consumer on the product's real identity or origin. From a legal point of view "counterfeiting consists in the violation of an intellectual property right protected by law, particularly by reproducing by copying or imitating a design, an invention, a trademark or a model protected by an intellectual property right"⁵ without its owner's consent. In the case of consumer goods, "a counterfeit is an identical reproduction or a fraudulent imitation including deception: the counterfeiter's aim is to create confusion between the original product (counterfeited) and the imitation he proposes (counterfeit). (...). Let us be clear that, in some cases, consumers are themselves fooled but they may also become a counterfeiter's accomplice by knowingly buying fakes".⁶ On the other hand, it should be noted that in the case of counterfeit medicines, the patient is rather the victim and rarely the accomplice in the purchase, at best they are foolhardy enough or misled by third parties to order medicines on websites which do not have all the necessary guarantees.

Where the definition is concerned, a medicine may be defined as "any substance or compounds presented as having curative or preventive properties with regard to human diseases. Any substance or compound which may be administered to humans with a view to establishing a medical diagnosis or to restore, correct or modify physiological functions in humans is also considered as a medicine".⁷ It should also be noted that a medicine is not a product like any other. To date, it is certainly the product most subject to control from its creation and its development, but also during its marketing phase (pharmacovigilance).

Similarly to other cases of counterfeiting concerning everyday consumer products, the definition of the counterfeit medicine has for many years been linked to infringement of intellectual property rights. On reflection, this analysis is all the more relevant since a counterfeit medicine involves reproducing or imitating an authentic brand and also, sometimes, copying the product patented by the pharmaceutical company. Nevertheless, however justified this may be, this view to a large degree overshadows an essential consequence of fake medicine: health.

² Barbara Pick, *Accès aux médicaments et contrefaçon pharmaceutique en Russie post-soviétique*, L'Harmattan, 2006, L'Harmattan, p. 10.

³ Albert I. Wertheimer, Perry G. Wang, *Counterfeit Medicines Volume I: Policy, economics and Countermeasures*, ILM Publications, 2012, p. 1.

⁴ Eric Przyswa, *Cybercriminalité et contrefaçon*, FYP, 2010.

⁵ Ibidem.

⁶ IRACM, *Fiche Propriété Intellectuelle*, January 30, 2012.

⁷ WHO definition (WHO Drug Dictionary Enhanced) and the one in European Directive 65/65, source: IRACM, *Fiche Propriété Intellectuelle*, January 30, 2012.

Even though some laws have included health as a circumstance aggravating a violation of intellectual property, this parameter was only a component and not the determining element. Under these conditions, medicine counterfeiting is still closely linked to reproducing, imitating, importing and selling an intellectual property right without its holder's authorisation. As an extension to this infringement of intellectual property rights, the terms fake, illicit, counterfeiting and counterfeit have emerged. That said, limiting the concept of medicine counterfeiting to this simple legal aspect comes down to considering this phenomenon as ordinary counterfeiting while denying its singular and dangerous nature.

The challenge in finding an exact definition of 'counterfeit medicine' is confirmed by Jean-Christophe Marten Pérolin, a senior official at the OCLAEPS⁸: "The products proposed are not always counterfeits; there are also other forms of crime. It may mean stolen or diverted medicines, quackery or medicines which have no marketing authorisation. The process for protecting public health (and consequently consumers) is an added value in the protection of trademarks and patents. The danger to health is real and must be taken into account by all".

Gradually, the concept of falsification above all emerged and even if this concept is still relatively inaccurate in its application, falsification may be defined as the "voluntarily altering (a substance or any other elements) with a view to misleading". Paradoxically, even if the intrinsic elements have been defined within the scope of falsification (fraudulent portrayal of its identity, of its source), counterfeiting is still the term used in numerous cases. On this subject, the most significant example is the definition deriving from the Médicrime convention, which defined falsified medicines but still kept the term counterfeiting for convenience. This semantic inaccuracy is also to be found in the definition of the IMPACT⁹ group's work in Hammamet (Tunisia) in December 2008. According to the IMPACT group, whose Secretariat is provided by WHO: "A medical product is counterfeited when its identity and/or its source is falsely portrayed. This applies to the product, its packaging or to any other information concerning the packaging or labelling. Counterfeit may apply to patented products or generic products. Counterfeit products may be products containing the right ingredients/components or bad ingredients/components, no active ingredient or an insufficient quantity of the active ingredient or products whose packaging was falsified".¹⁰ But in actual fact, in this case this is indeed the definition of a 'falsified' medicine.

The term falsification, compared with the term counterfeiting, by emphasising the risks of an impact on public health, makes it possible to go beyond a simple infringement of an intellectual property right. Furthermore, this concept avoids the difficult equation between the territoriality of intellectual property rights, access to medicines and the tricky issue of generics.

Preference is therefore given to the term 'falsification' rather than the more legal 'counterfeiting' to emphasise the risks of impact on public health.

In this context, the best definition would be the one in the European Directive of May 16, 2011¹¹ which defines a falsified medicine as:

"Any medicine which falsely presents at least one of the following characteristics:

- its identity, including its packaging and labelling, its name or the composition, regarding any of its ingredients, including the excipients, and the dosage of these ingredients;
- its source, including its manufacturer, its country of manufacture, its country of origin or that of its marketing authorisation holder;

⁸ Philippe Collier, "L'OCLAESP cible toutes les problématiques liées à la santé publique", Contrefaçon Riposte, December 18, 2009.

⁹ IMPACT: International Medicines Products Anti-counterfeiting Task force. The IMPACT Secretariat is provided by WHO. Group without any activity at present.

¹⁰ IRACM, Fiche Propriété Intellectuelle, January 30, 2012.

¹¹ Amending directive 2001/83/EC establishing a community code on medicines for human use with regard to preventing falsified medicines being introduced into the legal supply chain.

- its history, including registrations and documents concerning the distribution circuits used.

This definition does not include unintentional quality defects and is understood as being without prejudice to violations of intellectual property rights”.

This directive must be incorporated into the national legal systems of the European Union Member States by January 2013 at the latest.

Moreover, a distinction should be made between the concepts of counterfeiting and falsification in other cases:

- The “**sub-standard medicine**” or the “**non-compliant medicine**”:

Even though there is no legal definition for them, sub-standard medicines (called 'OOS' -out of specification) are authentic medicines produced by manufacturers authorised by the national regulatory authority but which do not meet the quality specifications set for them by national standards for such products. The term 'non-compliant' means that a medicine partially deviates from the specifications set by the registration dossier approved by the registration authority and/or good manufacturing practices in force in the country of registration. It is also important to make a distinction between defective products and counterfeit medicines as, according to Médecins sans Frontières, problems with defective products are more widespread.¹² The definition of a defective product is close, even identical, to that of a 'sub-standard medicine'. There are many causes for the defect, which may include the holder of the right and its potential sub-contractors. Not conforming to the standards of quality and traceability does not constitute counterfeiting but is rather a potential consequence of this.

- “**Fake medicines**”:

There is no proper definition of a 'fake medicine'. The term is occasionally employed, and is used in the Cotonou Appeal of the Jacques Chirac Foundation. A fake medicine is one that is not what it claims to be and is intended to mislead the consumer.

- “**Generic medicines**”:

Generic medicines are authorised copies of an original drug (brand-name drug). These copies are permitted by law once the patent protecting the active ingredient of the reference drug has expired, i.e. 20 years after the patent is filed and not 20 years after the product's launch (sometimes there are several years between the two dates), and unless an extension is granted by an SPC (supplementary protection certificate for a maximum duration of 5 years after the initial expiry date). Even though they are not totally identical to the originals, generic drugs have the same qualitative and quantitative composition in active ingredients, the same pharmaceutical form and the same bioavailability in the body as the brand-name drug.

Generic medicines are regulated, controlled and require a marketing authorisation (MA). Accordingly, they are not a problem for public health and we should note that generic medicines can also fall victim to counterfeiting.

In short, “the problem with counterfeit medicines lies in the wider context of sub-standard pharmaceuticals. (...) Counterfeiting can apply to both brand-name and generic products and counterfeit medicines may include products with the correct active ingredients but fake packaging, or other active ingredients, no active ingredient or insufficient active ingredients”.¹³

In such a complex environment, the concept of counterfeit medicines must be harmonised¹⁴ as the most widely accepted definition is the previously mentioned WHO definition but this dates back to 1990. It should be updated

¹² Jean-Michel Caudron et coll, “Substandard medicines in resource-poor settings: a problem that can no longer be ignored”, *Tropical Medicine and International Health*, vol. 12, No. 8, August 2008, p. 1062-1072.

¹³ AllAfrica.com, “Médicaments de qualité inférieure ou contrefaits - 25% des produits consommés dans les pays pauvres sont des contrefaçons”, *All Africa*, August 25, 2006.

¹⁴ Amir Attaran, Roger Bate and Megan Kendall, “Why and How to Make an International Crime of Medicine Counterfeiting”, *Journal of International Criminal Justice*, vol. 9, No. 4, 2011.

as, according to this definition, counterfeit medicines involve brand-name products and generic products as well as products containing appropriate or dangerous ingredients. In this case, counterfeit products may therefore be 'professional' or 'semi-professional', even 'amateur'.

The Council of Europe's definition is different from that of WHO in that it takes into account the counterfeiter's intentional nature in the definition and the portrayal of the counterfeit product. In this definition, it is not necessary to establish proof that the author's behaviour was actually detrimental to public and individual health.

The importance of the intentional nature is to be found in the field where a distinction is rarely made between counterfeit medicines and unintentional defective medicines, and according to a report made in South-East Asia¹⁵, quality defects are more frequent (10% of medicines analysed) than counterfeits according to the WHO definition (from 0.3 to 0.5% of medicines analysed).

As we have noted, the problem of defining counterfeiting is particularly evident in the case of medicines, particularly on an international scale. As Graham Jackson, editor of *The International Journal of Clinical Practice*¹⁶ recently summarised: "among the obstacles to adopting effective measures, the lack of any clear worldwide consensus on what constitutes a counterfeit medicine, as well as the fact that activities that are illegal in one country may be legal in another". More generally, a distinction should also be made in the analyses between the parameter on the health and public health impact and that of intellectual property¹⁷.

Consequently, particular caution is necessary in the field of statistics on counterfeit medicines and we will sparingly use the statistics given in a large number of reports, as quantifying this phenomenon on a world-wide, even regional scale, is delicate to say the least.

I.2. State of play

Counterfeiting medicines is a world-wide phenomenon, for example fake medicines for malaria and tuberculosis are present in 90 countries and kill 700,000 people each year.¹⁸ The areas most affected are Africa, Asia and Latin America. The Center for Medicines in the Public Interest¹⁹ estimates that the sale of counterfeit medicines reached USD 75 billion in 2010, i.e. an increase of 90% since 2005 while the overall turnover in the pharmaceutical sector increased from USD 605 to more than USD 856 billion in 2010²⁰. A more recent figure from the World Economic Forum²¹ even evaluates counterfeit medicine sales at approximately USD 200 billion, i.e. the leading sector for illicit trafficking ahead of prostitution and marijuana. Even if it proves impossible to provide reliable world-wide statistics on this situation²², it can nevertheless be estimated that the sales of counterfeit medicines over this period increased by 20% more than the legal market world-wide. In fact, it must be considered that the only sound statistical data concerns seizures made by customs.

¹⁵ Marcus M. Reidenberg, Bradley A. Conner, "Counterfeit and substandard drugs", *Clinical Pharmacology & Therapeutics*, vol. 69, No. 4, April 2001, p. 189-193 cited in Waito Foundation, *Le crime-contrefaçon : Un enjeu majeur*, 2011, p. 285.

¹⁶ Bulletin of the World Health Organisation, *The growing threat from counterfeit medicines*, vol. 88, No. 4, April 2010, p. 241-320.

¹⁷ Amir Attaran, Roger Bate and Megan Kendall, "Why and How to Make an International Crime of Medicine Counterfeiting", *Journal of International Criminal Justice*, vol. 9, No. 4, 2011, p. 947-951.

¹⁸ Julian Harris, Philip Stevens, Julian Morris, "Keeping It Real - Protecting the world's poor from fake drugs", *International Policy Network*, May 2009, p. 4.

¹⁹ Ibidem.

²⁰ Sources: IMS, Health Market Prognosis, March 2010 and Health Market Prognosis, March 2011.

²¹ World Economic Forum, Global Risks, Sixth edition, An Initiative of the Risk Response Network, 2011, p. 23.

²² Randall W. Lutter, Associate Commissioner for Policy and Planning, Food and Drug Administration, "Pharmaceutical Supply Chain Security", *Statement before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources, House Committee on Oversight Government Reform*, July 11, 2006.

There are three focuses on which the world-wide dimension of counterfeit medicines may be observed: the physical flows, the organisation of illicit trafficking and the Internet.

- Geography of the physical flows

According to researcher Roger Bate less than 1% of medicines are counterfeit in developed countries (United States, United Kingdom, and Europe)²³ are counterfeit and approximately 10% in a large number of developing countries (Russia, China, Cambodia).

However the 'dark figure' is considerable and sources are limited. According to the WHO IMPACT programme:²⁴

- one in 3 medicines is counterfeit in some African, Asian or Latin American countries,
- one in 5 medicines is counterfeit in the former Soviet Union.
- China, India and, to a lesser extent, Russia remain the main producers of counterfeit medicines but Nigeria and the Philippines also have a significant number of illegal factories.²⁵

By geographic area²⁶, Asia is significantly dominant by number of incidents:

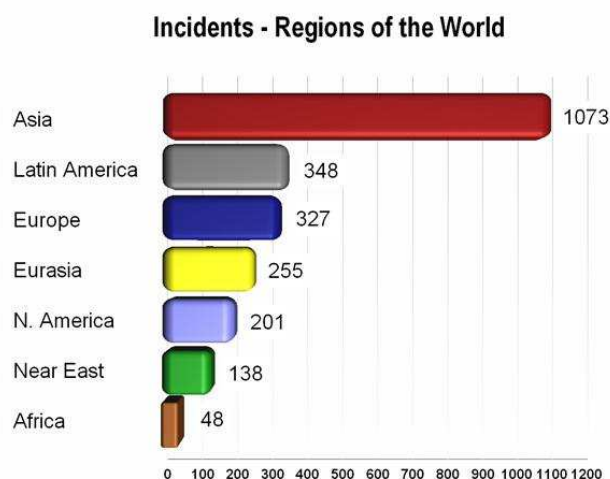


Figure 1: Incidents by region.
Source: Pharmaceutical Security Institute, *Situation Report*, 2010.

The Pharmaceutical Security Institute (PSI) uses specific terminology where cases of counterfeit medicines are referred to as "incidents" (according to the WHO definition) but also include stolen items and illegal diversions. These statistics are submitted by pharmaceutical companies who are members of the PSI.

²³ Roger Bate, *Making a Killing*. The Deadly Implications of Substandard and Counterfeit Drugs, Wellcome Trust presentation, October 26, 2009.

²⁴ IMPACT, *Counterfeit medicines, Fact sheet, Estimates*, November 14, 2006. It should be noted that the overall figures are debatable.

²⁵ See Commonwealth Business Council Working Group on Healthcare, *The Problem of Counterfeit Medicines in the Commonwealth*, May 2007, p. 2.

²⁶ Pharmaceutical Security Institute, *Situation Report*, 2010.

According to its methodology, the PSI only takes into account seizures of more than one thousand medicine doses. The statistics concerning Africa are quite poor (45 incidents referenced), stemming from the inadequate means of detection and investigation in this part of the world.

In 2009, according to the PSI, Asia and Europa were the two main regions involved in manufacturing counterfeit medicines. According to the OECD, 75% of counterfeit medicines in the world come from China and India and half of these products transit through Dubai to conceal their origin.

- Organisation of illicit trafficking

This trafficking is characterised by a variety of strategies depending on the regions, the increasingly dangerous nature of the counterfeit medicines as well as an ever-greater number of seizures.

Strategies varying depending on the regions

More specifically, there are three stages in the medicine counterfeiting process:

- Production:

The counterfeit medicines can be produced in an emerging country such as China but, in certain cases, in more developed countries which are happy to import for example the starting material at a lesser cost.

- Transit:

This may be by sea but air, road and rail transport may also be used or medicines even carried by travellers. The storage areas may have no relation to the country of origin, which tend to cover their tracks. Furthermore, similarly to world transport, particularly by container, goods may transit through countries, be stored in free trade zones, be transhipped to other means of transport, and in this way enable the real origin of the goods to disappear so that only their declared origin remains.

At all stages, the counterfeiters try to maximise fragmentation so as to avoid being detected (see the 'broken load technique' page 34).

- Distribution:

The products are often distributed through various shell companies which take advantage of local relay networks but may also be distributed directly within legal economic networks through well-known companies. In this way, they can be directly incorporated into the mainstream medicines distribution chain as far as the delivery outlet, or quite simply, in certain countries, made available on street markets or the Internet.

In industrialised countries the packaging of counterfeit medicines is identical to that of authentic medicines. The easy access to high-quality low-cost mass production printing systems is also behind an increase in internet counterfeiting. "Counterfeiters know that the key to success is making the packaging as realistic as possible, then distributing the products as quickly as they can".²⁷ The marketing channels are international and counterfeiters take advantage of deregulation to penetrate a given market after passing through several countries. According to the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) counterfeiting a 'blockbuster' (medicine generating sales of more than one billion dollars for the pharmaceutical company) can generate a profit in the region of USD 500,000 for an initial investment of USD 1,000²⁸ while the same initial sum invested in the trafficking of counterfeit money or heroin would bring in USD 20,000 and USD 43,000 for counterfeit cigarettes. Drug counterfeiting is 10 to 25 times more profitable than drug trafficking.²⁹

²⁷ Andrew Baxter, "The war on drugs copycats", *Financial Times*, December 19, 2006.

²⁸ Report written under the direction of Eric Schmidt, *Evaluation de l'ampleur de la vente des produits contrefaisants sur internet*, CEIS, March 2009, p. 56.

²⁹ IRACM, Fiche Criminalité organisée, January 30, 2012.

In poor and developing countries, counterfeit medicines are of poor quality and dangerous to human health. It is very often in these countries that dangerous ingredients are found, such as the cough syrup containing anti-freeze for motor vehicles which killed 84 Nigerian children (2009).³⁰

In these countries, counterfeit medicines are found locally, for instance at markets or in hospitals. The counterfeit products are often also intended to treat potentially lethal illnesses, such as malaria or HIV/AIDS. These products are also copycat antibiotics, analgesics or antiparasitics.³¹

In Nigeria, six out of 10 medicines sold have not been approved and in Guinea, 60% of the medicines sold in pharmacies are counterfeit.³²

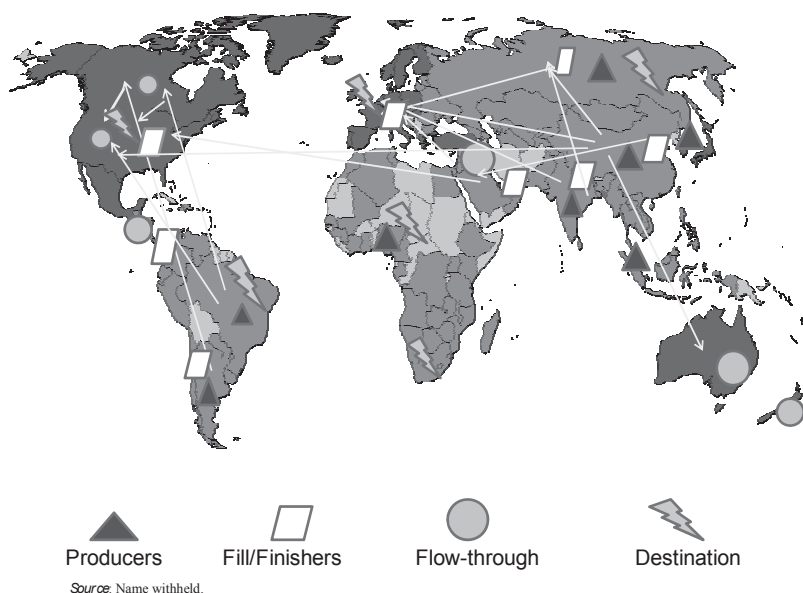


Figure 2: Example of the manufacturing and distribution flow of counterfeit products
Source: OECD, *The economic impact of counterfeit and piracy*, 2008³³

Counterfeiting is a world-wide problem. According to the WCO (World Customs Organization), 140 countries are targeted.³⁴ Counterfeiting has become globalised.

It should be noted that information on the Chinese factories involved and their sometimes dubious methods are still not well documented. A few years ago it was estimated “that China has 80,000 firms in the chemical sector but the U.S. Food and Drug Administration does not know how many of them sell ingredients used in the medicines taken by Americans. The *Times*, which examined thousands of firms selling products on the major B2B sites, succeeded in identifying 1,300 Chinese firms in the chemical sector offering medical ingredients for sale”.³⁵

³⁰ Blandine Fauran, “Les enjeux de la lutte contre les faux médicaments”, *Cahiers de la sécurité. Les dangers de la contrefaçon*, No. 15, January-March 2011.

³¹ Ibidem.

³² Pierre Delval, *Le marché mondial du faux. Crimes et contrefaçons*, CNRS éditions, 2010, p. 153.

³³ OECD, *The economic impact of counterfeiting and piracy*, 2008, p. 361.

³⁴ World Customs Organization, *Customs and IPR Report*, 2008.

³⁵ Walt Bogdanich, “Chinese drugs flow to market unchecked”, *International Herald Tribune*, November 1, 2007.

The genuinely dangerous nature of counterfeit medicines

These medicines are truly dangerous and we should remember that, even if they do not actually kill, counterfeit products, whether over-dosed, under-dosed or without any active ingredient, do not cure. Therefore, at best, a counterfeit medicine fails to cure the patient and, at worst, it is deadly. Somewhere in between, it can lead to drug resistance, which may result in treatment failure. From a more concrete standpoint, the WHO referenced a series of major accidents and particularly the case of injections of counterfeit products to treat anaemia that killed a young Argentinian woman in 2004.³⁶

There are other examples that may be cited:

- In 2006, more than 100 children in Panama were victims of a counterfeit medicine containing diethylene glycol, a powerful solvent, added to a fake cough syrup. The solvent was falsely identified and exported as glycerine, an ingredient used in a large number of medicines³⁷.
- Singapore: the health authorities recorded 11 deaths and 24 coma cases after taking counterfeit medicines for sexual dysfunction in 2008-2009.³⁸
- China: 192,000 deaths from counterfeit medicines in 2001 (400,000 deaths since 2001 according to Pharmaciens sans Frontières in Luxembourg).³⁹

The risk to public health from counterfeit medicines is expanding: counterfeit seizures in 2009 during the 'Storm 2' operation, co-ordinated by IMPACT in Asia, ranged from antibiotics to contraceptives, tetanus vaccines, anti-malaria medicines and treatments for erectile problems. In Egypt, investigators have found products of all types: from medicines used in organ transplants to those prescribed for disorders such as heart disease, schizophrenia and diabetes, as well as thousands of packs of cancer medicines.⁴⁰ The PSI estimates that about 523 medicines were counterfeited in 2012.⁴¹

A growing number of seizures

According to the WCO, the trafficking of counterfeit medicines increased by 300% between 2007 and 2009⁴². In 2009, 117 million medicines were seized by customs in Europe⁴³, 18 million of which were dangerous. Seizures of counterfeit medicines are becoming more and more varied.⁴⁴ (anti-inflammatory drugs, pain killers, antiseptics, medical equipment (stethoscopes, etc).

³⁶ IMPACT, Counterfeit medicines, Fact sheet, November 14, 2006.

³⁷ IRACM, Fiche Enjeux : Stopper une pandémie planétaire, January 30, 2012.

³⁸ Sylvia Tan, "Counterfeit sex drugs: 11 deaths and 24 coma cases", Friday, September 18, 2009.

³⁹ Pharmaciens-sans-frontieres.lu, "Les médicaments contrefaits", Pharmaciens Sans Frontières Luxembourg, May 22, 2011. We will come back to the validity of these statistics later on.

⁴⁰ Comments by Aline Plançon, Interpol in the Bulletin of the World Health Organisation, vol. 38, April 2010, p. 241-320.

⁴¹ Kathy Chu, "Growing problem of fake drugs hurting patients, companies", USA Today, September 13, 2010.

⁴² IRACM, Fiche Criminalité organisée, January 30, 2012.

⁴³ Christophe Zimmerman, co-ordinator of the combat against counterfeiting and piracy at the WCO, Conférence sur la contrefaçon à la Mutualité française : Le trafic de faux médicaments comment le combattre, October 15, 2010.

⁴⁴ Interview with Jean-Christophe Marten Pérolin, senior official at OCLAESP, by Philippe Collier, "Douanes : 7 million d'articles contrefaisants saisis en 2009", Contrefaçon Riposte, April 23, 2009.

Between 2009 and 2010⁴⁵, the number of shipments intercepted by customs almost doubled: it went from 43,500 in 2009 to almost 80,000 in 2010, with health products representing respectively 18% and 14.5% of the total.

These substantial figures can be explained by the huge increase in the number of illicit postal parcels intercepted, almost 50,000, which were purchases on the Internet. Germany (22,125) and Great Britain (22,146) each made almost 30% of these interceptions. In France, customs seizures mainly concern fake tablets for erectile dysfunction. That said, these figures should be put into perspective as, at the same time, it should be remembered that smaller quantities of this type of product are despatched.

In the United States, the customs authorities also seize increasing quantities of counterfeit medicines. Hence, their market value was assessed at USD 16.8 million in 2011 compared with USD 5.7 million the previous year, i.e. an increase of 200%.⁴⁶ In financial terms, these medicines represent 10% of total seizures compared with 3% in 2010.⁴⁷

The number of investigations conducted by the FDA (Food and Drug Administration) concerning cases of counterfeit medicines went from 6 in 2000 to 58 in 2008⁴⁸. Products potentially dangerous to the health and safety of consumers represented 10% of seizures made in 2008 at a value of USD 28 million.⁴⁹

There are several reasons for the increase in the number of seizures of counterfeit medicines⁵⁰:

- High profitability and low penal risk.
- Technological progress (particularly in printing).
- Globalisation mechanisms.

Internet: a major distribution vehicle

International trans-organised crime has very quickly understood the substantial advantages that the internet has to offer. The net is decentralised and anonymous and the malleability and permanent interconnection of networks seems to offer genuine opportunities for illicit trafficking.

On the whole, e-commerce is increasing considerably world-wide and counterfeit medicines can therefore find a real growth potential in cyberspace. Even if there are still very few studies concerning the internet, a certain number of results portray the reality of the phenomenon:

- according to the WHO, 50% of the medicines are bought on web sites which conceal their physical address⁵¹,
- according to a study⁵² carried out by the European Alliance for Access to Safe Medicines, 62% of medicines bought on the internet are counterfeits (50% according to the WHO).

⁴⁵ European Commission - Taxation and customs union, *Report on EU customs, enforcement of intellectual property rights Results at the EU border*, 2010. Source: Philippe Collier, "Europe : En 2010, les douanes ont saisi pour plus d'un milliard d'euros de contrefaçons aux frontières de l'UE", *Contrefaçon Riposte*, July 15, 2011.

⁴⁶ U.S. Customs and Border Protection, U.S. Immigration and Customs Enforcement, *Intellectual Property Rights, Fiscal Year 2011 Seizure Statistics*, 2011.

⁴⁷ Ibidem.

⁴⁸ Leem.org, "La contrefaçon dans les pays industrialisés", *LEEM*, May 19, 2010.
<http://www.leem.org/article/contrefacon-dans-les-pays-industrialises>

⁴⁹ Ibidem.

⁵⁰ Mickaël R. Roudaut, *Marchés criminels. Un acteur global*, Presses Universitaires de France, 2010, p. 133.

⁵¹ Bulletin of the World Health Organisation, "Growing threat from counterfeit medicines", vol. 88, No. 4, April 2010, p. 241-320.
<http://www.who.int/bulletin/volumes/88/4/10-020410/fr/index.html>

- 90% of counterfeit medicines now sold on the Internet⁵³ are fakes⁵⁴ and according to a Japanese study⁵⁵, 60% of medicines treating erectile dysfunction on the Internet are counterfeits.

Some elements per geographic area

- United States

In the United States, 36 million Americans⁵⁶ bought medicines without a prescription on illegal sales sites and the Internet has become the leading distribution channel for counterfeit medicines in this country.⁵⁷ A more worrying statistic cited by the American firm OpSec Security⁵⁸: 66% of Internet users are prepared to knowingly buy counterfeit products and 90% of people interviewed gave the price as the main criterion for buying such products. Such information challenges the claim that the patient is always the victim and not the accomplice when buying a fake medicine or, at least, is very foolhardy. Sites offering medicines for sale in America often emphasise their Canadian nationality even though there are only 300 legal Canadian on-line pharmacies. Furthermore, according to the International Chamber of Commerce, more than 11,000 fake sites using a 'Canadian cover' are in actual fact based in other countries (often in Russia and India).⁵⁹

- Europe

The regulations adopted by the various governments to implement the new European directive vary greatly⁶⁰ from one country to another. Based on the *Doc Morris*⁶¹ order from the Court of Justice of the European Union (CJEU) of December 11, 2003, online marketing of products without a prescription is now authorised.

One unique study serves as a reference: the 'Cracking Counterfeit Europe'⁶² study conducted in 14 European countries concludes that the European market for counterfeit medicines is worth around EUR 10.5 billion annually. In France, the market is worth almost EUR 1 billion.

⁵² Agence France Presse, "Les médicaments vendus sur Internet inquiètent", *EAASM*, July 2, 2008.

The study concerns the analysis of 100 on-line pharmacies and the purchase of 30 medicines.

⁵³ Indo-Asian News Service, "Beware, 44 percent Viagra sold on net is spurious", *IANS*, January 26, 2010.

⁵⁴ *Ibidem*.

⁵⁵ Pharma-japan.com, "60% of ED Treatments Sold Online Are Counterfeits", *Pharma Japan*, December 21, 2010.

⁵⁶ Pnewswire.com, "36 Million Americans have Bought Medications Online Without a Doctor's Prescription", *PR Newswire*, December 14, 2010.

⁵⁷ National Intellectual Property Rights Coordination Center, Intellectual Property Rights Violations: A Report on Threats to United States Interests at Home and Abroad, November 2011, p. 31.

⁵⁸ OpSec Security, Press release, OpSec Identifies High Quality and Product Functionality as Key New Drivers Motivating Online Counterfeit Electronic Sales, July 8, 2009.

⁵⁹ International Chamber of Commerce, Counterfeiting Intelligence Bureau, The International Anti-Counterfeiting Directory, 2009, p. 25.

⁶⁰ Philippe Collier, "L'OCLAESP cible toutes les problématiques liées à la santé publique", *Contrefaçon Riposte*, December 18, 2009.

⁶¹ The company Doc Morris offered German consumers, in German, medicine for human use, part of which were authorised in Germany and the majority of which were authorised in other member states of the European Union. The Court held that the prohibition to sell medicines online without authorisation is justified and for those which need a prescription. On the other hand, mail-order sales of medicines that do not need a prescription and their advertising cannot be prohibited.

⁶² Mypharma-editions.com, "Les faux médicaments représenteraient 10,5 milliards d'euros en Europe", *MyPharma Editions*, February 16, 2010.

This study, carried out by Nunwood on behalf of Pfizer Inc. shows that, in Europe, one out of five persons surveyed, i.e. 77 million individuals, acknowledges buying prescription medicines outside the authorised channels. In France, it was 14% of those interviewed, i.e. 6.9 million people.

- *France*

France is still safeguarded in Europe, thanks to the quality of the healthcare system, the strong regulations governing pharmaceutical activities and thanks to the system of reimbursement for prescription drugs. However, risks are now emerging in connection with “purchases of counterfeit so-called 'comfort' products on the internet, slimming pills, food supplements, performance-enhancing drugs or anabolic agents sought by bodybuilding enthusiasts”.⁶³

Between 2001 and 2008, some 40 pharmacovigilance cases relating to the use of internet medicine purchases were reported to the Afssaps⁶⁴. Out of 38 cases identified, 11 concerned purchases of slimming products, 3 anabolic steroids, and 8 stimulants or revitalizing products, particularly hormone-based.

- *Switzerland*

Switzerland is sometimes used as a strategic area for trafficking counterfeit medicines at European level. In 2011 the director of Swissmedic⁶⁵ pointed out “a strong rise in the illegal imports of medicines potentially dangerous for patients”. According to customs authorities, seizures of illicit products rose to 61% compared to 2009. More than a third of the counterfeits were stimulants treating erectile problems.

The counterfeit medicines most frequently purchased online⁶⁶ are mainly medicines against erectile dysfunction, but also slimming products, anabolic agents, growth hormones, melatonin, products to quit smoking and also narcotics and psychotropic substances.

With regard to the slimming products sold on the internet, a Swissmedic study⁶⁷ showed that almost 90% contain active ingredients that are a dangerous health threat.

In light of this assessment of counterfeit medicines, how can a more specific analysis be made of the criminal organisations involved in this ever-growing illicit trafficking?

I.3. Criminal organisations and counterfeiting

The concept of criminal organisations should be determined and the logic of ‘structural holes’ used by such organisations when counterfeiting medicines.

This survey was carried out between October 27, and November 8, 2009. 14,000 men and women in 14 European countries took part in it. Countries concerned: United Kingdom, Belgium, Switzerland, Spain, Norway, Denmark, Sweden, Austria, Germany, France, Italy, Netherlands, Finland and Ireland.

⁶³ Philippe Collier, “L’OCLAESP cible toutes les problématiques liées à la santé publique”, *Contrefaçon Riposte*, December 18, 2009.

⁶⁴ Philippe Collier, “L’Afssaps démontre les dangers des médicaments vendus sur Internet” *Contrefaçon Riposte*, January 13, 2009.

⁶⁵ Elisabeth Eckert, “Berne lance l’alerte contre les faux Viagra”, *Le Matin*, 20 F2011.

⁶⁶ Blandine Fauran, “Les enjeux de la lutte contre les faux médicaments”, *Cahiers de la sécurité. Les dangers de la contrefaçon*, No. 15, January-March 2011.

⁶⁷ Swissmedic, Press release, Résultats d’analyse alarmants: Nouveaux chiffres sur des produits amincissants dangereux vendus sur Internet, June 6, 2011.

I.3.a. Definition of criminal organisations

The expression 'organised crime'⁶⁸ first appeared in 1897 in the United States and developed during prohibition. The concept is generally associated with "rackets, extortion, predatory activities and the supply of illegal goods. Interest in it revived during the 1960s with the spread of the drug dealing which grew at an unprecedented rate in the United States".⁶⁹ This view of organised crime influenced the European approach, particularly from the 1970s, with "a view of organised crime which is moving towards a more violent model, more professional and multinational".⁷⁰

There are two main definitions⁷¹ of organised crime:

- The Council of Europe (1998) describes criminal organisations as "a structured group of more than two persons, established over a period of time, acting in concert with a view to committing offences which are punishable by deprivation of freedom or a detention order of a maximum of at least four years or a more serious penalty, whether the offences are an end in themselves or a means of obtaining material benefits and, where appropriate, of improperly influencing the work of the public authorities".
- The definition of criminal organisations with the greatest consensus is that of the United Nations Convention against Transnational Organised Crime (Palermo, December 2000)⁷², which defined an "organised criminal group" as a "structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes in order to obtain, directly or indirectly, a financial or other material benefit".

From a more theoretical standpoint, we note moreover that "this transition from multiple to single definition raises many questions, particularly concerning the appropriateness of the legal standard in relation to the phenomena that we wish to comprehend (...) but also (...) its purposes and its functions".⁷³ Consequently, a definition of 'organised crime' as flexible as the one decided at Palermo still raises the question of adapting the 'legal standard' on how organisations are perceived and treated. Another issue with the definition: the 'transnational' dimension. This aspect of the definition is not quite as simple as it appears and the question of relations between criminal organisations and the international economy was a subject for debate among researchers in the 1960s. It was in 1975, at the fifth United Nations congress on 'Crime Prevention and Criminal Justice' that the expression 'transnational crime'⁷⁴ took on its full magnitude, particularly by going into the details of the complex links which may exist between conventional organised crime, major economic actors and corrupt institutional representatives. That said, little effect seems to have resulted from this pertinent review of the situation, particularly on the type of relations in question between these actors, which has nevertheless not dampened academic debates often out of touch with the real issues.

This transnational dimension is obvious to an initial category of researchers. According to the economist Loretta Napoleoni⁷⁵ "a new economy of terror has emerged" and for the journalist Claire Sterling there is a "Pax Mafiosa" with criminal organisations which peacefully share territories on a world-wide scale.⁷⁶ A more 'networked' view of

⁶⁸ We will not make a distinction between the expressions 'criminal organisation' and 'organised crime' in this report.

⁶⁹ Bleuzenn Monot, *La guerre de la contrefaçon. Le grand pillage des marques*, Ellipses, 2008, p. 77.

⁷⁰ Maria-Luisa Cesoni, *Criminalité organisée : des représentations sociales aux définitions juridiques*, LGDJ, 2004, p. 622.

⁷¹ IRACM, *Fiche Criminalité organisée*, January 30, 2012.

⁷² Source of the definition: United Nations Convention of November 15, 2000.

⁷³ Maria-Luisa Cesoni, *Criminalité organisée : des représentations sociales aux définitions juridiques*, LGDJ, 2004, p. 5.

⁷⁴ Vincenzo Ruggiero, "Fuzzy criminal actors: Introduction", *Crime, Law & Social Change*, vol. 37, No. 2, p. 177-190, 2002.

⁷⁵ Franck G. Madsen, *Transnational Organized Crime*, Routledge, 2009, p. 80.

⁷⁶ Claire Sterling, *Crime Without Frontiers*, Little, Brown and Co, 1994.

international mafia groups⁷⁷ is favoured by the sociologist Manuel Castells⁷⁸, a specialist in information technologies, who sees in these mafia organisations “a global network”. Within a more geopolitical approach, the academic Susan Strange, who considers that there “is a form of transnational mafia diplomacy which has given rise to a proliferation of informal agreements denoting the existence of an international mafia society just as a State one”.⁷⁹

Another category of researchers has a more critical view and considers this transnational dimension of organised crime as ‘hypothetical’ and “to obtain additional resources or to extend their prerogatives, it is naturally of interest to the enforcement authorities to present the criminal organisations as powerful, threatening and hungry to extend their activities and influence”.⁸⁰

In the context of today's globalised economy, these two views however appear to be somewhat exaggerated as we will see that, at the very least, this transnational dimension of crime is obvious. According to the most credible researchers,⁸¹ it is important to challenge the ‘conspiracy views’ as the alliances in question between so-called transnational criminal groups are above all “temporary opportunistic alliances”⁸² and their structures are still not particularly ‘formalised’. Criminal organisations (and ‘mafias groups’ even more so) in fact must see themselves as not particularly structured as, according to the expression of the academic, Jean-Louis Briquet⁸³, they are “an object with indeterminate outlines, a reality constantly avoiding the definitions suggested for them (...) *a constantly changing moving phenomenon*, forcing a corresponding change in the models which try to comprehend it”.

As for the ‘critical approach’, even if it raises pertinent questions on the direction in which certain enforcement agencies may or may not be going, in its analyses it neglects access to the crime sources which, even if they are difficult to access, may to a certain degree be available particularly on problems as specific as ‘counterfeit medicines’.

Generally speaking, one should avoid falling victim to sensationalism or being taken in by the frequent incorrect information on criminal organisations not only in the media but sometimes also in the academic environment.⁸⁴ The whole difficulty therefore lies in having comparative research work on a study subject as complex as criminal organisations, as “although the attempt to unequivocally identify an ‘organised crime’ subject, enabling international comparative research to be developed, was made by various researchers⁸⁵, it resulted in “an impossibility being recognised, based on the over-diversity of the phenomena generally grouped together under these names”.⁸⁶ The organised nature of the phenomenon is particularly difficult to determine.

⁷⁷ There are many definitions and academic debates about the mafia. In the original sense, the term means the Sicilian mafia but in the wide sense it means any form of organised crime in other geographic areas (Russian, Japanese mafia, etc.). The mafia may be defined as a criminal organisation whose activities are subject to concealed collegial management and which is based on a strategy of infiltrating civil society and institutions. Source Wikipedia: September 15, 2012.

⁷⁸ Manuel Castells, *End of Millennium*, Oxford: Blackwell Publishers, 2000, p. 172.

⁷⁹ Richard Friman, “Prise au piège de la folie ? Le pouvoir étatique et le crime organisé transnational dans l’œuvre de Susan Strange”, *Culture & Conflits*, No. 42, summer 2001.

⁸⁰ Gilles Favarel-Garrigues, “La criminalité organisée transnationale : un concept à enterrer ?”, *L’Economie politique*, No. 15, July 2002.

⁸¹ Jean-Louis Briquet or again Mark Galeotti may be cited.

⁸² Mark Galeotti, “Introduction: Global Crime Today”, *Global Crime*, vol. 6, No. 1, February 2004, p. 1-7.

⁸³ Jean-Louis Briquet, “Comprendre la mafia. L’analyse de la mafia dans l’histoire et les sciences sociales”, *Politix*, vol. 8, No. 30, 1995, p. 139.

⁸⁴ Roderic Broadhurst, Naryanan Ganapathy, “Organized Crime in Asia: A Review of Problems and Progress”, *Asian Criminology*, vol. 3, No. 1, June 2008, p. 1-12.

⁸⁵ Maria-Luisa Cesoni, *Criminalité organisée : des représentations sociales aux définitions juridiques*, LGDJ, 2004.

⁸⁶ *Ibidem*.

A complexity probably mainly due to globalisation, as it must not be perceived as “a technological extension”,⁸⁷ particularly with the impact of the Internet, but rather as a “social process which configures and reconfigures “relations between multiple entities (...) which are widely spread over the area”.⁸⁸ An interpretation which tends to prove *the wide variety of social organisations present and therefore the multiplicity of potential criminal organisation models*.

For all that, should it be considered that we are faced with a form of analytical stalemate?

A Council of Europe report on crime⁸⁹ qualifies this stalemate and considers that “the concept of organisations with a clearly defined hierarchy seems increasingly to give way to one with criminal networks made up of individuals or small units, as well as legal structures (most often commercial) and experts of all types (lawyers, accountants, etc.) more or less closely affiliated to these structures. (...) In short, the criminal networks can function by adapting to market conditions and by exploiting the possibilities offered to them”. However, beyond this flexible organisational structure, it remains true that criminal organisations, particularly in counterfeiting, may be described as “economic extremists, who are looking for profit any way they can”.⁹⁰

Although globalisation has transformed the traditional models of criminal organisations, even made them more complex, from this point of view, medicine counterfeiting is a stimulating study area which will enable us to question and shed light on ‘organised crime’ – and therefore the concepts of ‘crime’ and ‘organisation’ – under a new and pragmatic angle.

1.3.b. Criminal organisations and counterfeit medicines: a ‘structural hole’ logic

Whatever definitions of criminal organisations are accepted (Council of Europe or Palermo), the trafficking of counterfeit medicines most often meets each of the criteria common to both⁹¹:

- several persons involved,
- the existence of a real structure within the group,
- the violations committed or intended are serious,
- the criminal activity is stable over time.

But this view of the criminal organisation appears to be too ‘static’ as many criminal organisations, particularly where medicines are concerned, seem to be formed on ‘organisational flaws’. A point of view more particularly conceptualised by the American sociologist Ronald S. Burt⁹², who theorised on the concept of “structural holes”⁹³ which appear “when there is a gap between two persons with a complementary need in terms of resources and information”.⁹⁴ A third party is then necessary and acts as a sort of entrepreneur, bringing together the two separate individuals and closing the existing gap. This ‘social bridge’ then enables the entrepreneur to make a

⁸⁷ David S. Wall, *Cybercrime. The Transformation of Crime in the Information Age*, Polity Press, 2007, p. 37.

⁸⁸ Maureen Cain, “International crime and globalisation”, *Criminal Justice Matters*, vol. 46, No. 1, 2001.

⁸⁹ Council of Europe, *Organised crime situation report: Focus on the threat of economic crime*, 2005.

⁹⁰ Bertrand Monnet, Philippe Véry, *Les nouveaux pirates de l'entreprise : Mafias et terrorisme*, CNRS éditions, 2010, p.173.

⁹¹ IRACM, *Fiche Criminalité organisée*, January 30, 2012.

⁹² Ronald S. Burt, *Structural Holes. The Social Structures of Competition*, Harvard University Press, 1992.

⁹³ Ming Xia, “Organizational Formations of Organized Crime in China: perspectives from the state, markets, and networks”, *Journal of Contemporary China*, vol. 17, No. 54, 2008, p. 1-23.

⁹⁴ Ronald S. Burt, *Structural Holes. The Social Structures of Competition*, Harvard University Press, 1992.

profit. In the field of counterfeit medicines the counterfeiters may be extremely skilful at locating the ‘social holes’ within the supply chain.

The following diagram (based on food fraud) may also be applied to crime in counterfeit medicines.



Figure 3: Criminal opportunities based on the Felson triangle.

This diagram is based on the Felson criminal triangle⁹⁵ which identifies three elements offering opportunities for crime: the criminals, the victims and the “guardians and protectors of gaps”. ‘Guardians’ should be understood as the police, customs, NGOs, etc. and by ‘protectors’ as systems intended to monitor product traceability, watch techniques, etc. Above all, the importance of the gaps and ‘structural holes’ for fraudsters is seen here. No matter how skilled the ‘guardians’ or ‘protectors’ may be in reducing the risks of counterfeit, the opportunities for crime cannot be entirely controlled and they have probably increased with globalisation and the liberalisation of international trade over the past 20 years. However, similarly to food fraud⁹⁶, detecting counterfeit medicines is complicated as the counterfeiting criminals can multiply the ‘entry points’ thanks to the numerous ‘gaps’ that the logistics flows offer them.

From the more operational standpoint, it can be seen that the medicine counterfeiters use the “broken load” technique⁹⁷ which makes it difficult to seize the goods. This technique consists in “routing a counterfeit product to its final destination and passing it through one or more third party countries which, as far as possible, are not considered to be countries producing counterfeits in that particular field. In this way, the counterfeiters hope that

⁹⁵ Marcus Felson, Ronald V. Clarke, *Opportunity makes the thief: practical theory for crime prevention*, Police research series, Paper 98. London: Home Office, 1998.

⁹⁶ Douglas C. Moyer, John Spink, “Defining the Public Health Threat of Food”, *Journal of Food Science*, vol. 76, No. 9, 2011.

⁹⁷ Mark Davison, *Pharmaceutical Anti-Counterfeiting. Combating the Real Danger from Fake Drugs*, Wiley, 2011, p. 18.

the customs will focus on where the product has come from and not its origin".⁹⁸ Furthermore, the counterfeiters use every means of transport possible and divide up the manufacturing and packaging stages. Such operations make it difficult to trace the goods as "counterfeit medicines may be manufactured in one country, processed in another, packaged in a third before they are shipped in transit via various countries to arrive at last at the destination where they are intended for sale".⁹⁹ These criminal organisations also tend to perfect their medicines' packaging rather than the content, giving priority to deceiving the customs services on the products' origin.¹⁰⁰ On a large scale, these networks of counterfeiters also have the capacity to produce fake quality conformity certificates for the medicines or other fake official documents enabling them to infiltrate the legal wholesaler or distribution networks. Control of the distribution network is generally the key factor for the most powerful criminal organisations.¹⁰¹ Moreover, it can be noted that these problems of intermediation and traceability of pharmaceutical products are hardly new and that, in the 19th century, control over the products sold already gave rise to fears of counterfeiting at that time.¹⁰²

This question of flows more generally poses the problem of the manufacturing and distribution network. The American system, with its complex network of distributors and wholesalers, offers a great many opportunities for a criminal organisation specialised in counterfeiting to enter into this maze of flows by identifying the weak points. As the diagram below¹⁰³ shows, the three main American wholesalers which distribute 90% of medicines in the United States (AmeriSourceBergen, Cardinal Health Inc., and McKesson Corp.) are in contact with pharmacies then consumers and can also potentially be the target for the flow of counterfeit products. The risk particularly comes from 6,500 small secondary wholesalers which can be targeted by counterfeiters.¹⁰⁴

⁹⁸ Ibidem.

⁹⁹ Barbara Pick, *Accès aux médicaments et contrefaçon pharmaceutique en Russie post-soviétique*, L'Harmattan, 2006, p. 128.

¹⁰⁰ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 29.

¹⁰¹ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 146.

¹⁰² Gérard Béaur, Hubert Bonin and Claire Lemerrier, *Fraude, contrefaçon et contrebande de l'Antiquité à nos jours*, Droz, 2007, p. 717.

¹⁰³ Wyatt Yankus, prepared for The American Council on Science and Health, *Counterfeiting drugs: coming to a pharmacy near you*, updated version, 2009, p. 6.

¹⁰⁴ Roger Bate, *Making a Killing: The Deadly Implications of the Counterfeit Drug Trade*, The AEI Press, 2008, p. 28.

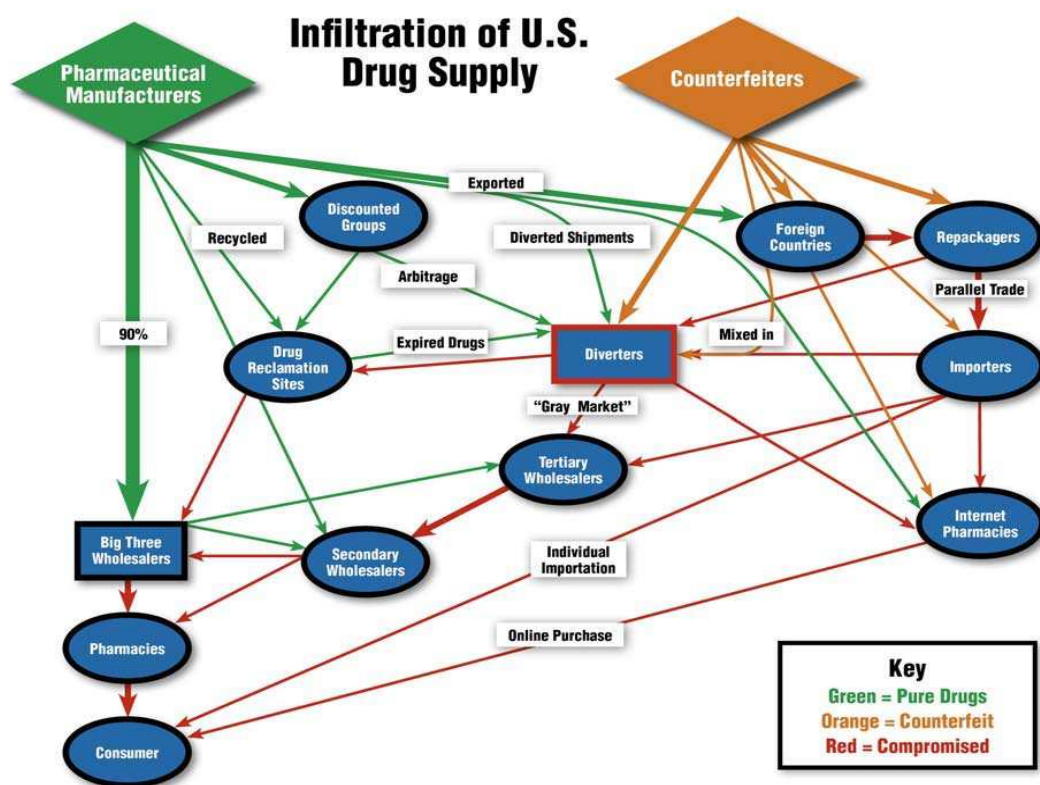


Figure 4: Example of manufacturing and distribution flows of counterfeit products. Infiltration of U.S. Drug Supply.

As figure 4 shows, the counterfeiters seek to integrate the supply chain legally. To do this, they can mix the real and fake products and repackage counterfeit products.

The aim is to avoid arousing the suspicion of the three main American wholesalers by mixing legal and illegal products and by fragmenting the chain as much as possible thanks to secondary wholesalers who are less particular about the products' origin, making it even more difficult to trace back to the source.

Generally speaking, the United States is a priority target for counterfeiters as, according to estimates, 40% of medicines are imported there, thereby increasing the potential risk of importing counterfeit medicines.¹⁰⁵

These problems are also to be found in Europe, in particular in Switzerland¹⁰⁶, which may sometimes be an intermediate zone at risk, especially due to its permeable borders with the European Union.

In fact, even if imports of medicines directly intended for the Swiss population are tightly monitored, this is less the case for exports to European countries.¹⁰⁷ According to Hans-Beat Jenny, deputy director of Swissmedic, the Swiss Institute for therapeutic products, favourable economic and tax conditions make Switzerland an attractive country for traders in somewhat dubious medicines, and despite rather strict local practices with regard to authorisations. "That's just the way it is", admits the deputy director of Swissmedic. "It is often noticed that the real origin of fake medicines has been concealed".¹⁰⁸

¹⁰⁵ Nabp.net, "National, International Stakeholders Develop New Strategies for Fighting Counterfeit Drugs", NABP, May 3, 2011.

¹⁰⁶ Julie Zaugg, "La Suisse leader des faux médicaments", *L'Hebdo*, May 29, 2008.

¹⁰⁷ Ibidem.

¹⁰⁸ Ibidem.

Trying to trace these commercial routes proves to be difficult¹⁰⁹. That said, there is no doubt that ‘commercial’ flows of counterfeit medicines exist between Asian countries such as China and India and Europe and North America. It is obvious that there are unscrupulous European and North American importers who exploit the opportunities offered by the parallel market as we have seen with the cases of Peter Gillespie in Great Britain or Andrew Strempler in Canada. These importers set up dangerous entry points within legal supply chains. It is all the more complicated to backtrack along these commercial routes since the supply chain may be particularly sophisticated and the counterfeiters may have various ways of integrating them.

The criminological environment also has a special significance in the case of counterfeit medicines as we saw that the criminal organisations are difficult to identify. White-collar crime, sometimes linked to an industrial environment or immersed in a legal environment, can offer opportunities to set up illicit networks in medicines. Sometimes a major analytical challenge arises which is of course linked to the fact that such organisations are more or less secret as well as access to sources of information both confirmed and relevant. This work does not claim to be an exhaustive view but to open up strong lines for analysis with the most credible sources (media, academics, interviews). Fieldwork and subsequent work could of course extend this initial analysis to where crime and the pharmaceutical sector meet since it should be kept in mind that criminal-counterfeiting methods and organisations are permanently evolving¹¹⁰. In addition, this research work should be considered not as a definitive study on a complex and opaque phenomenon but rather a ‘snapshot’ which also tries to clarify a field of thought, to a large degree as yet untouched. The case of cybercrime reveals analytical challenges on the combination of ‘criminal organisations and counterfeit medicines’.

I.4. Cybercrime and counterfeiting

I.4.a Definition

Similarly to the many debates on the definition of crime, cybercrime does not evade definition problems, which particularly stem from the difficulty in identifying this form of Internet crime. Among the many proposals is the one put forward by the United Nations¹¹¹: “cybercrime means any illegal behaviour using electronic operations which target the security of computer systems and data they process”. Olivier Iteanu¹¹², a lawyer specialised in new technologies, proposes a definition widely shared by the majority of actors: “cybercrime can be defined as any illegal action in which *a computer is the instrument or the subject of the offence*”.

However, as Olivier Iteanu makes clear, this definition has the disadvantage of not taking what is ‘offline’ into account¹¹³. That said, the customs and a certain number of actors tend to widen the concept of cybercrime to include actions which involve criminal flows *both in reality and on the Internet* by means of a computer. This wider view of cybercrime is accepted as it has the advantage of enabling this form of crime to be observed both in a real and a virtual field. Indeed, it is evident that if an order is placed on the Internet, inevitably it is physically delivered.

¹⁰⁹ UNICRI, Counterfeiting, A Global Spread, A Global Threat, 2007, p. 39.

¹¹⁰ Nayanah Siva, “Tackling the booming trade in counterfeit drugs”, *The Lancet*, vol. 376, November 20, 2010.

¹¹¹ Myriam Quémener, Joël Ferry, *Cybercriminalité, défi mondial et réponses*, Economica, 2007, p. 4.

¹¹² Olivier Iteanu, *Tous cybercriminels*, Jacques-Marie Laffont éditeur, 2004.

¹¹³ ‘Offline’ here may be assimilated with the so-called physical world contrary to the virtual world embodied by the Internet.

The question remains¹¹⁴ as to whether cybercrime as such is actually a new form of avant-gardist criminality or if it is only a medium for more conventional forms of crime.¹¹⁵ According to this point of view, the concept of cybercrime ‘swings’ between the new and the conventional which “raises a difficulty from the definition’s theoretical standpoint”. The Canadian researcher, Stéphane Leman-Langlois, makes a distinction between simple computer crime and cybercrime which involves a more dynamic use of the Internet network and within which the concept of cybercrime covers conduits whose existence is entirely linked to that of the networks. This *dynamic view of the networks* is particularly relevant for the continuation of our reflections on the issues of counterfeit medicines on line.

1.4.a Types of cybercrime

Since the 1990s, cybercrime has been characterised by its “automatic and dispersed” nature¹¹⁶ thanks to broadband technology. In the 2000s, there was a substantial increase in cybercrimes with growing specialisation in technology:

Spam: this may be defined as “unsolicited bulk email. Unsolicited means that the recipient has not granted verifiable permission for the message to be sent. Bulk means that the message is sent as part of a larger collection of messages, all having substantively identical content”.¹¹⁷

The despatch of these emails is often “an instrument starting the execution of a main violation enabling substantial profits to be made illegally”.¹¹⁸

This technique can be used in certain cases of online counterfeiting, in particular for medicines.

Phishing is a “method for fraudulent gathering of individual and personal data from Internet users with a view to using it to the detriment of the customers of banks and commercial websites”. This technique consists in taking advantage of Internet users’ gullibility to obtain, for instance, their credit card number by means of fake emails using official logos (FBI or a famous bank).¹¹⁹

As for pharming, it is an offshoot of phishing and involves rerouting access to a website towards a pirate site. Even if the site’s address seems to be correct, the Internet user is in fact rerouted to a bogus site where the hacker can then capture confidential information.

*Cybersquatting*¹²⁰ is a practice which consists in registering an Internet domain name (most often taking the name of a known brand), then selling it back with profit to the legitimate owner of this name. Depending on the way the domain name is used, this technique can have certain similarities with counterfeiting, unfair or parasitic competition.

¹¹⁴ Stéphane Leman-Langlois, “Questions au sujet de la cybercriminalité, le crime comme moyen de contrôle du cyberspace commercial”, Centre International de Criminalité Comparée, Université de Montréal, *Criminologie*, vol. 39, No. 1, spring 2006, p. 63-81.

¹¹⁵ It should be noted that according to the British reference academic David S. Wall, the majority of cybercrimes which come to court in fact are classic criminal activities rather than a presumed new type of cybercrime in David S. Wall, “The internet as a conduit for criminal activity” in April Pattavina (ed.), *Information Technology and the Criminal Justice System*, Sage, 2004.

¹¹⁶ Franck Guarnieri, Eric Przyśwa, “Cybercriminalité - contrefaçon : les interactions entre ‘réel et virtuel’”, *Cahiers de la sécurité. Les dangers de la contrefaçon*, No. 5, January-March 2011.

¹¹⁷ Source: The site of the international organisation The Spamhaus Project, <http://www.spamhaus.org/consumer/definition/>

¹¹⁸ Joël Ferry, Myriam Quémener, *Cybercriminalité, défi mondial et réponses*, Economica, 2007.

¹¹⁹ According to the sources quoted by researcher Eric Filiol, about 5% of targeted Internet users fall into the traps set by phishers. Eric Filiol, Philippe Richard, *Cybercriminalité, enquête sur les mafias qui envahissent le web*, Dunod, 2006, p. 41.

¹²⁰ CEIS definition, Source: Eric Schmidt (dir.), *Evaluation de l’ampleur de la vente des produits contrefaisants sur internet*, CEIS, March 2009.

Typosquatting (or typowriting) consists in registering a domain name whose spelling is very similar to that of another name which has the advantage of substantial traffic. If Internet users accidentally enter an incorrect website name, they may be rerouted to the site owned by the cybersquatter.

As for cyberspace, two features may describe it¹²¹:

- A permanent interaction between real and virtual (an essential point which is also extremely relevant to the analysis of a cybercrime relating to counterfeiting).
- A spatiality specific to it since it is a moving landscape, a relational territory constantly being reconfigured which gives priority to gateways and 'connectivity'.

To summarise, cybercrime is evolving in an emerging territory where computer threats are carried out specifically in relation to the real world but where the interaction between virtual and real is still essential for analysis particularly in the case of a product with high added value such as a medicine.

The moving dimension of cyberspace makes the observation of cybercrime all the more strategic since there are 2.2 billion Internet users in the world.¹²²

¹²¹ Solveig Godeluck, *La géopolitique d'internet*, La Découverte, 2002, p. 7-8.

¹²² Internet World Stats, December 31, 2011.



II. Realities of the « counterfeit medicines and criminal organisations » combination

Before moving onto the specific case of counterfeiting, it should be made clear that criminal organisations are also involved in the theft or diversion of medicines to the black market. A recent case in Canada¹²³ is significant of this situation: almost 3 million painkillers were stolen or mysteriously disappeared from Canadian pharmacies over three years, of which more than 200,000 were doses of opiates in Quebec. The others were above all 'lost in transit' or were 'inexplicably lost'. Two products are particularly prized by thieves: "oxycodone (...) and hydromorphone".¹²⁴ These two products enable the production of medicines belonging to the opiates class, which include all those deriving from the poppy, including heroin, opium and morphine and can therefore in part be of interest to drug addicts. The origin of this trafficking may be varied: thefts from pharmacies, fake prescriptions, thefts from a wholesaler or from an importer's premises, even from customs.

With regard to counterfeiting, the links between counterfeit medicines and organised crime today seem to be widely acknowledged particularly by UNICRI¹²⁵ as well as by Interpol¹²⁶. As far as trafficking is concerned, it is confirmed that this involvement in counterfeit medicines is managed to varying degrees by organised crime. "The criminal organisations have seized the opportunities inherent to global changes. They have developed a competitive advantage and governments are today incapable of setting up effective strategies to combat a crime which is both delocalised and globalised".¹²⁷ Hence, organised crime has a new face that increasingly resembles a transnational firm's trade which combines a rigid hierarchy and a territorial presence with flexible structures that can be adapted depending on the circumstances.

These organisations which meet the criteria laid down by the United Nations Palermo Convention (2000)¹²⁸ above all want to profit financially from these serious offences. A financial profit that we will see is increasingly substantial in medicine counterfeiting. As for the structure of the groups in question, the diversity of cases can be observed, with prominence given to networked organisations over those with a more highly structured hierarchy. The size parameter appears to be the most significant indicator of the criminal nature of such organisations: cybercrime will confirm such a network approach sometimes on a large scale but with more marked organisational fragmentation and with one individual's capacity to commit crimes potentially on a world-wide scale.

Generally speaking, these criminal organisations will also tend to sustain their activities over time to generate even more profits with an ever-growing risk to health.

Several types of criminal organisations may be distinguished in medicine counterfeiting:

- small-sized organisations,
- medium-sized transnational organisations,
- large-scale and particularly transnational organisations which can last for several years and change depending on constraints/opportunities,
- cybercriminal organisations.

¹²³ Daphné Cameron, "Opiacé des million de pilules disparues", *LaPresse.ca*, June 6, 2012.

¹²⁴ *Ibidem*.

¹²⁵ UNICRI, Counterfeiting, A Global Spread, A Global Threat, 2007, p. 103.

¹²⁶ "The link between organised crime groups and counterfeit products is well established". Public speech made by R. K. Noble on July 16, 2003 to the International Relations Commission of the United States House of Representatives ([www. interpol.com](http://www.interpol.com)).

¹²⁷ *Ibidem.*, p.105.

¹²⁸ Source of the definition: United Nations Convention of November 15, 2000.

As we will see, a strategic category is linked to this typology: the case of Chinese crime which combines crime linked to a grey economy with the triads whose involvement, despite everything is still difficult to demonstrate accurately in our field of research. We will also discuss the question of mafia groups and links with terrorism.

II.1. Small-sized criminal organisations (two to five persons)

This type of organisation is generally to be found in a western country where an individual imports counterfeit medicines from China or India either alone (or with two or three accomplices). These organisations are often people who sense the opportunity to make money by proposing specific products for a section of the population at attractive prices. Among the many examples that can be cited is the case of Englishman Victor Cheke¹²⁹, 42 years old, who was questioned by agents of the UK Border Agency at Coventry airport when he arrived with packets containing tens of thousands of counterfeit pills to treat erectile dysfunction. Cheke had initially contemplated simply importing these 'medicines' then planned on distributing them afterwards on the Internet and selling the tablets at 25 pence per unit. The Englishman was in financial difficulties and, in this illegal trade, saw a fast way of earning money. He had a previous history as he illegally imported 29,000 tablets from India in 2009 and was given a one-year prison sentence.

There is also the case of Mimi Trieu¹³⁰, the owner of a beauty salon in Philadelphia, who imported and sold slimming pills from October 2008 to May 2009 and continued to import them up to March 2010, even though she was well aware that these pills contained sibutramine and other dangerous substances. Almost four million pills were imported from China by post in this way: the parcels stated that the contents were gifts with a non-commercial value.

According to the American authorities, Mimi Trieu sold 1,750,000 capsules of illegal medicines at a value of USD 245,000. Furthermore, she promoted these fake pills stating that they were manufactured in Japan and contained natural ingredients... All incriminating evidence.¹³¹

In the case of China, there is the example of Lu Chong¹³², a 27-year old Chinese man from Tianmen City, in the province of Hubei, who was sentenced to 11 years in prison for having sold almost a hundred types of counterfeit medicines on the Internet (especially to treat diabetes, gout and depression) in 2007 and 2008. When his apartment was inspected, more than 5,000 bottles of medicines were confiscated as he did not have a licence to manufacture medicines. His sales were estimated at CNY 1.4 million (USD 220,000) in two years. The investigators had to travel to 20 Chinese towns over three years to collect proof from 400 victims in order to prove his guilt.

Even if France is still protected, and no counterfeit medicines have been seized in legal pharmacies, nevertheless trafficking can be organised particularly with Chinese channels. In an investigation, the SNDJ¹³³ established the involvement of a couple¹³⁴ who, from 2006 to 2008, ran a family network to procure medicines for their Paris shop and several illegal pharmacies in Paris. "They also used frontmen to conceal the illegal import of medicines and the financial transfers between France and China. The couple and their accomplices were questioned in May 2008. 7,600 boxes, representing more than 400 medicines, were seized in their Paris

¹²⁹ Matthew Cooper, "Man jailed for faked Viagra imports", *TheIndependent.co.uk*, September 9, 2011.

¹³⁰ FDA, Philadelphia Woman Pleads Guilty to Importing Illegal Diet Pills, December 17, 2010.

¹³¹ Source of information, Website: http://www.justice.gov/usao/pae/News/Pr/2010/may/trieu,m_indictment.pdf

¹³² Xinhua News Agency, Chinese court gives heaviest sentence for selling fake drugs on Internet, October 10, 2009.

¹³³ SNDJ: French National Judicial Customs Service

¹³⁴ Case cited in: Leem, French Customs, Press release, Lutte contre les trafics de médicaments, le Leem et la Douane renforcent leur coopération et signe une déclaration de principes avec les laboratoires pharmaceutiques, June 18, 2010.

shop. Only pharmacists have the right to sell these medicines. Some of them, particularly those treating sexual dysfunctions, were counterfeits or were forbidden due to their toxicity (risks of hypertension or renal failure)".¹³⁵

These types of case confirm that ordinary people increasingly have access to criminal activities thanks to widely accessible technological tools and international commercial flows.

II.2. Medium-sized transnational criminal organisations (about 10 persons)

Three big cases can be distinguished in this category: the Wuppertal and Arnaud B. cases (both of them still on-going) and the Peter Gillespie case, which is a major health risk. These examples prove that medium-sized organisations can stem both from international organised crime (Wuppertal) and actors more directly involved in the pharmaceutical industry (Gillespie) or an opportunistic wheeler-dealer (Arnaud B.).

II.2.a. Wuppertal case¹³⁶

This case started in February 2007. At that time, a German received a parcel containing medicines addressed as 'return to sender' that he had never posted. This German informed the authorities and in May 2007 the regional police set up a surveillance system around the Wuppertal central post office which seemed to be where counterfeit products were sent from to potential patients. In July 2007, almost 18,000 parcels containing medicines, i.e. 1,300 kilos of various brands, were intercepted in Wuppertal warehouses after only four months of surveillance. The parcels seized contained tablets in bulk packed in sachets with a photocopy of the leaflet sent to American patients who had ordered their medicines on two supposedly American Web sites (www.usamedz.com and www.pillenpharm.com) but which in fact are domiciled in the Netherlands and Israel. Furthermore, the online payments routed the patient to a third site called rxsecured.com, shared by the former sites, hosted in Israel. Finally, the money was paid into a bank in Panama.

In August 2007, the authorities made test purchases on the site www.usamedz.com which confirmed that the medicines were counterfeit. The investigation proved that the goods were manufactured in China then imported to a warehouse in Italy. Four suspects were then arrested, the ringleader of which was an Israeli. The value of the goods seized was estimated at EUR 450,000 in cash or equipment. The value of the post sent was valued at about USD 4 million. Two other Bulgarian suspects, responsible for the logistics and post, were located in Salzburg in Austria. Finally, a last suspect was from Georgia and Israel. A number of countries were used for the logistics: Italy for storage and the transfer of counterfeit medicines and Germany for packaging the orders intended for American patients.

The goods were then sent by post from France to the United States.

The payment system turned out to be complex and transited through various countries: Germany, Cyprus, Austria then Switzerland. A Georgian bank was also involved in money transfers. Two central points in the organisation were in Israel and the British Virgin Islands.

This case is similar to organised crime which is characterised by "the temporary nature of the groups which spontaneously break up after a few operations or spontaneously disperse after some of their members have been arrested".¹³⁷ With the sole difference that the network was only dismantled temporarily as it was formed

¹³⁵ Ibidem.

¹³⁶ The name of the town has been changed.

¹³⁷ Christian Choquet, "Evaluer la menace terroriste et criminelle", Cultures & Conflits, February 25, 2005, p. 4.

again particularly in Spain. On the other hand, the three-fold skill in logistics, e-commerce and finance brings this organisation very obviously close to a managerial system.

II.2.b. Arnaud B. case

A second recent large-scale case with a central actor: the Arnaud B. case¹³⁸.

Since 2007, Arnaud B. is suspected of having disposed of more than 4 tonnes of counterfeit medicines manufactured in China through official pharmacies in the United Kingdom, and also in Germany, Belgium, Switzerland, the United States the United Arab Emirates.

“He had medicines manufactured that were either under-dosed or had no active ingredient at all, according to a source close to the case. These products were intended to combat cardiovascular diseases and treat people who suffered from bipolar disorder”¹³⁹. The damage to pharmaceutical companies, including Sanofi, came to several million euros. The suspect, the owner of a villa in Spain, bought EUR 14 billion in cash, was served a European arrest warrant before being presented to the Spanish judicial authorities. He is expected to be handed over to an examining magistrate in the specialised inter-regional court in Marseilles, in charge of this case. “This operation, called Casamayor, the name of the company managed by Arnaud B. in Spain, was made possible thanks to the collaboration between the investigators of the Guardia Civil and the gendarmes in the OCLAESP (*French central office for combatting dangers to the environment and public health*), the same source went on to say. This international dealer in medicines had become the number one priority”.¹⁴⁰ The French investigators traced back to him after the American health authorities, during clinical trials, found anomalies in the composition of several medicines treating cardiovascular diseases and schizophrenia delivered by Arnaud B. “Without this, he would have continued his little businesses for a long time” revealed someone close to the case. One of his accomplices was questioned in the United States and was given a six-year prison term. One of his intermediaries in France was also identified before being questioned”.¹⁴¹ Catherine K., director of a company based in Nice, responsible for reshipping part of the counterfeit goods, was formally accused with dealing in ‘counterfeit medicines’, ‘laundering’ and ‘illegal practising the profession of pharmacist’, before being put under judicial supervision. These pills were resold in packaging very similar to the originals and with the same name as the genuine medicines. The investigations are being continued to establish the destination of the money amassed by this dealer.

II.2.c. Peter Gillespie case

Peter Gillespie is 65-year old Englishman, originally from Windsor, Berkshire who managed a Luxembourg-based company. Between December 2006 and May 2007, this chartered accountant and pharmaceutical distributor imported 72,000 packets of counterfeit medicines, i.e. more than two million doses¹⁴². Approximately one-third of these shipments concerned medicines presumed to treat serious conditions such as prostate cancer, heart problems and schizophrenia. His company imported medicines for an amount of GBP 1.4 million while they had a retail value of GBP 4.7 million and, hence, the profit earned by all the partners came to GBP 3 million (USD 4.9 million).

¹³⁸ Stéphane Sellami, “Le trafiquant avait écoulé quatre tonnes de faux médicaments” *Le Parisien*, October 10, 2012.
<http://www.leparisien.fr/espace-premium/actu/le-trafiquant-avait-ecoule-quatre-tonnes-de-faux-medicaments-10-10-2012-2219347.php>

¹³⁹ Ibidem.

¹⁴⁰ Ibidem.

¹⁴¹ Ibidem.

¹⁴² Chris Greenwood, Neil Sears, “Fake cancer drugs given to thousands: Conman jailed for importing two million doses”, *Daily Mail on Line*, February 1, 2012.

The counterfeit medicines were shipped from China by sea via Hong Kong, Singapore and Belgium, then packaged as French medicines to be sold in Great Britain under the 'parallel distribution'¹⁴³ system.

According to the MHRA¹⁴⁴, this was the first major case where counterfeiters used this distribution technique. In this enormous fraud, 25,000 packets of counterfeit medicines were sold to pharmacies or hospitals and were therefore available to patients.¹⁴⁵ A contributing factor: according to the MHRA these 'medicines' only contained 50 to 80% of active ingredients plus impurities of an unknown nature.

Gillespie put forward¹⁴⁶ that he thought he had imported French medicines from Brussels and that he was therefore legally practising 'parallel trade' and taking advantage of the price differences between the countries. But the medicines in question did not have the social security price tags for reimbursement specific to France and were in boxes labelled in Chinese. The MHRA gave even less credence to these arguments since Gillespie's claims were rapidly refuted by the fact that the Englishman had also bought machines to make the French social security tags and to make it appear that they were from France.

Peter Gillespie was sentenced to eight years in prison and four other men were also accused of being his accomplices (his brother Ian Gillespie, Richard Kemp, Ian Hardling and James Quinn). According to the prosecutor Andrew Marshall, this was the biggest case of failure in medical monitoring to occur within the European Union. The investigation cost the MHRA GBP 750,000 over four years.¹⁴⁷

II.3. Large-scale and transnational criminal organisations

According to the philosopher Peter Sloterdijk¹⁴⁸, with present-day globalisation there is "crime which is based on professionalised improved disinhibition, which continues to find new ideas in circumstantial loopholes. This sustainable crime is basically about sensing the loophole, a loophole in the market and a loophole in the law". All growth elements for transnational criminal organisations.

But it should also be made clear that studying transnational crime comes up against three major obstacles¹⁴⁹:

- the lack of any sound data,

¹⁴³ "The parallel imports of patent pharmaceuticals derive from the principle of free circulation of goods between the States party to the Agreement on the European Economic Area. Their legality was recognised by the Court of Justice of the European Communities in 1976. In practice, parallel imports may be briefly defined as a situation where an economic operator, independent of the official distribution channel of the marketing authorisation (MA) holder, acquires in a State party to the Agreement on the European Economic Area a patented medicine with an MA issued by the health authorities in this State*, with a view to its sale (...)*. *When the medicine has a European MA obtained through a centralised procedure, the term parallel distribution is used instead of parallel import.

Source: ANSM (French National agency for the safety of medicines and healthcare products). <http://ansm.sante.fr>

¹⁴⁴ MHRA: Medicines and Healthcare Products Regulatory Agency, British organisation responsible for combating counterfeiting.

¹⁴⁵ BBC.co.uk, Man jailed for £4.7m counterfeit medicine fraud, April 8, 2011.

<http://www.bbc.co.uk/news/uk-england-beds-bucks-herts-13020208>

¹⁴⁶ Nayanah Siva, "How investigators unravelled Europe's biggest-ever-fake-medicine scam", *Wired*, December 2011.

¹⁴⁷ Chris Greenwood, Neil Sears, "Fake cancer drugs given to thousands: Conman jailed for importing two million doses", *Daily Mail on Line*, February 1, 2012.

¹⁴⁸ Peter Sloterdijk, *Le palais de cristal : à l'intérieur du capitalisme planétaire*, Maren Sell Editeurs, 2006, p. 257.

¹⁴⁹ Robert Mandel, *Dark Logic, Transnational Criminal Tactics and global security*, Stanford Security Studies, Stanford University Press, 2010, p. 7.

- the difficulty in defining these transnational activities,
- ambiguity in trying to identify these transnational criminals and their organisations.

A considerable amount of work on transnational crime has barely taken these parameters into account and resulted in “numerous inaccuracies, simplifications, exaggerations and misconceptions”¹⁵⁰ of the issues.

That said, some criminal cases may reveal more sophistication in the organisation of counterfeit medicines. Even if the aforementioned cases of Wuppertal or Peter Gillespie are similar to ‘transnational criminal organisations’ with a structured but flexible organisation ‘on a human scale’, other cases may reveal networks of an unprecedented scope on a much more complex transnational scale. Two cases in this category are significant: the RxNorth case, and above all, the so-called ‘Jordanian-Chinese’ network, which became the ‘Avastin’ network, all of which have in common that they lasted for a long period (respectively, five years and about ten years).

II.3.a. RxNorth case

On May 22, 2006, the British customs at Heathrow airport seized a large quantity of the counterfeit version of medicines manufactured by major pharmaceutical companies. The goods originated in China, then went by truck to Hong Kong, by boat to Dubai and finally by plane to the United Kingdom, before being shipped to the Bahamas.

The medicines in question were intended for a company called Personal Touch Pharmacy based in the Bahamas. The shipment concerned eight different medicines, seven of which turned out to be counterfeit. These were not so-called comfort medicines but treatments for blood pressure, cholesterol and osteoporosis.

Following the investigations, the telephone number of the goods' recipient in the Bahamas, entered on the air transport document, and enabled Andrew Strempler, director of RxNorth, to be identified.



Andrew Strempler

Source: <http://updatednews.ca/2012/06/20/canadian-online-pharmacy-pioneer-denied-bail-in-u-s>

This company was founded by Strempler in Canada in 1999 and took advantage of flaws in the health system in the United States to specialise in online distribution of medicines intended for a niche in the American population with little or no insurance. In fact, the medicines ordered on the RxNorth site (now closed) did not originate in Canada but... China and took a complex commercial route.

On June 9, 2006, the Bahamian police investigated the company *Personal Touch Pharmacy* which turned out to be an RxNorth distribution centre. After the warehouses were raided, the Bahamas authorities found USD 3.7 million worth of goods concerning 13 pharmaceutical companies and more than 3 million dose units.¹⁵¹ According to the authorities, the annual revenues of *Personal Touch Pharmacy* (and therefore RxNorth) can be estimated at about USD 8 million.¹⁵²

This Bahamian company sent parcels of the goods, which originated in China, ordered by customers on its website. These orders were in fact accepted by two other companies in England which sent the goods directly

¹⁵⁰ Ibidem.

¹⁵¹ Bryan A. Liang, Tim Mackey, “Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales”, *American Journal of Law and Medicine*, vol. 35, No. 1, 2009, p. 125-184.

¹⁵² Ibidem.

by letter to customers living in Canada and, above all, in the United States. This simple rerouting operation enabled the English companies involved in this trafficking to earn a commission of USD 1 per packet. For its part, RxNorth placed orders for counterfeit products in China. The trafficking of counterfeit medicines was complex and transited through Hong Kong, the United Arab Emirates, Great Britain and Canada. The reason why these physical flows of goods were fragmented was to conceal the exact origin of the medicines which were then sold on to an illicit online pharmacy which was officially 'Canadian', targeting the American market. (see figure 5).

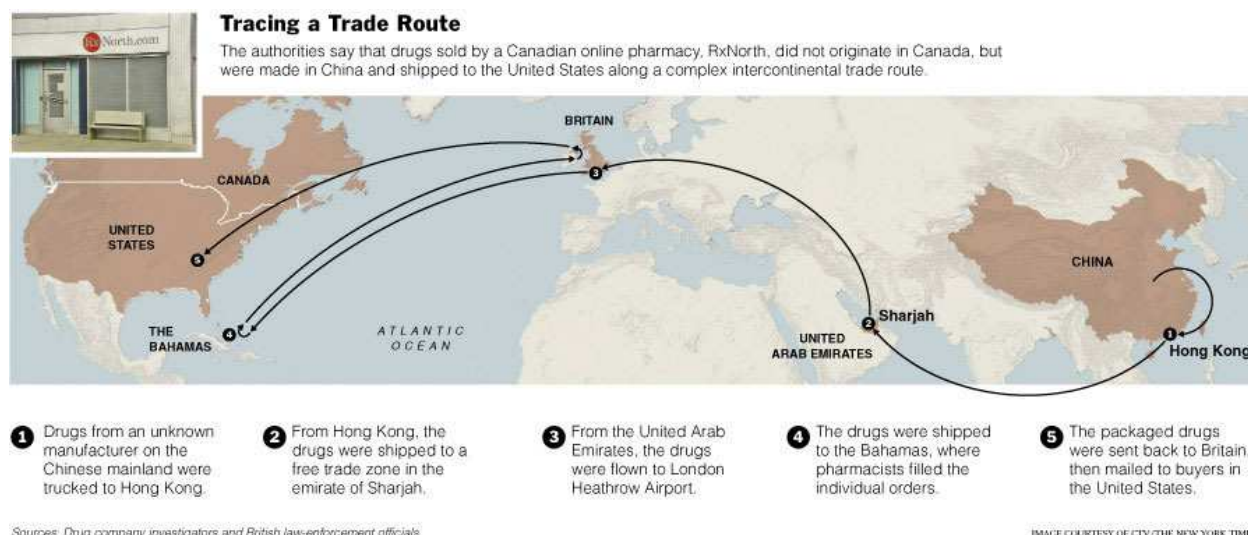


Figure 5: Counterfeit medicine trafficking - RxNorth

Source: Walt Bogdanich, "Free Trade Zones Ease Passage of Counterfeit Drugs to U.S." *The New York Times*, December 17, 2007

The investigators' task was a complex one: in this way, the licence number corresponding to the transport of the suspect medicines from mainland China to Hong Kong could not be used in an investigation. Another example, after the raid in the Bahamas, the counterfeiters moved the stocks of counterfeit medicines held in the Sharjah free trade zone within the United Arab Emirates to another free trade zone in Dubai called Jebel Ali. The goods were stored in a warehouse belonging to a trading house called Euro Gulf specialised in linen and cleaning.¹⁵³ When alerted, the Dubai customs found the suspicious medicines and charged seven people.

The searches made on the *Personal Touch Pharmacy* computers proved that their server also hosted a Canadian online pharmacy which belonged to RxNorth.

Faced with the charges against him, Andrew Strempler temporarily took refuge in Panama, but six years later, his situation changed:

- In August and September 2006, the FDA intercepted 5,000 packets from the online pharmacy and warned the Americans about buying 10 specific medicines (above all, anti-cholesterol treatments) as tests revealed that they were counterfeit.
- In 2007, the company was sold to a competitor, the CanadaDrugs.com Group of Companies. - In 2010, Andrew Strempler lost his pharmacist's licence in Manitoba.
- In June 2012, Andrew Strempler was arrested in Miami, Florida and runs the risk of a 60-year prison sentence.

¹⁵³ Walt Bogdanich "Free Trade Zones Ease Passage of Counterfeit Drugs to US", *The New York Times*, December 17, 2007.

Even though RxNorth used the Bahamas particularly as a distribution platform, the exact origin of the Chinese manufacturer or manufacturers involved in this trafficking is still unknown today.

But an even more complex case stemming from the Middle East deserves to be explained.

II.3.b. The 'Jordanian-Chinese' network

Two transnational channels embody the complexity of the counterfeiters' networks. The first channel is based in the Middle East with relations with China in particular, and the second channel – which partially stems from the first one – concerns counterfeit medicines exported from the Middle East to markets in western Europe and North America. Turkey played the role of intermediary between the two channels in question.

The first channel was originally developed at the time of the American invasion of Iraq in 2003. Two families, one Syrian and the other Jordanian, shared smuggling activities on both sides of the border, in Daraa and Ramsa. The chaos of the civil war in Iraq encouraged the two families to specialise in medicine counterfeiting activities (particularly treatments for leukaemia, breast cancer, etc.) to meet the Iraqi demand and in particular to supply to the country's main distribution structure for medicines: the company Kimadia¹⁵⁴. In fact, this company has proven to be a distribution structure subject to regular corruption.

A Jordanian, Wajee Abu Odeh, claims to be a central operator in the counterfeiting networks in the Middle East and went as far as setting up his own company, Sky Park Co. Ltd, in Shenzhen in China in July 2003, to be closer to the manufacturing sources of counterfeit medicines (officially his Shenzhen company is a subsidiary of his Hong Kong holding company, which operates in textiles, electronics and economic consulting). Married to two Jordanians, Abu Odeh had a third wife, Wu Xia, also born in Shenzhen, China, who helped him to set up his commercial structure locally. The fake *Sky Park Co. Ltd* medicines were sent by boat and above all by air from China to various hubs in the organisation: Dubai, Amman, Damascus then Cairo.¹⁵⁵

Amman was the most important hub, particularly for counterfeit medicines for aggressive treatments but Dubai was more involved in counterfeit comfort medicines. The majority of the medicines were sent by Emirates airlines which, once informed of this illicit trafficking, assisted the investigators in their inquiries. Fake official documents concerning the counterfeit medicines were given to customs, who were not particularly fussy about the exact origin of the products so that they could be imported. The medicines were then distributed according to a system similar to that for traditional drugs¹⁵⁶ by using hiding places in vehicles (tanks or false compartments) where the counterfeit medicines were concealed. These medicines were then redistributed in smaller quantities by 'human mules' towards the various Middle East borders. If the 'mules' were questioned by the customs authorities, they declared that these fake medicines were for their own use and, in the case where they were intercepted by local customs, one may wonder about their destination as no counterfeit medicine has ever been returned to its original laboratory.

In certain cases, the distribution techniques were particularly creative since counterfeit medicines were found in table tennis balls, hidden in washing machines or wrapped in T-shirts sent by sea. Between 2003 and 2006, the trafficking prospered in seven Arab countries: Iraq, Syria, Jordan, Lebanon, Egypt, the United Arab Emirates and the Palestinian territories.

In 2007-2009, the network developed substantially and distributed these counterfeit medicines in a large number of countries in the region.

¹⁵⁴ Kimadia, set up in 1964, is the only Iraqi company specialised in importing, storing and distributing medicines and medical devices and equipment for public and private hospitals or healthcare centres. Source: <http://www.kimadia-iraq.com>

¹⁵⁵ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 209.

¹⁵⁶ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 209.

- Jordan

The network is changing: initially it was dismantled in Jordan in 2007 with a first raid in Amman when the Jordanian security forces discovered four thousand packets of counterfeit medicines to treat blood pressure supplied by the Chinese company Sky Park.¹⁵⁷ At least 15 persons were arrested at that time but there were difficulties in proving their guilt. The individuals in question were released after two months and were sentenced to pay fines of between a few thousand dollars and USD 100,000, which was the case for Abu Afifeh, one of the network's key participants.

The network then extended into the Palestinian territories and afterwards into Egypt.

- Palestinian territories

In the Palestinian territories, the case took on particularly worrying aspects. In March 2008, a large number of counterfeit medicines (treating leukaemia for instance) were discovered at the main Palestinian medicines distributor, Al Thulathia. The tests carried out by Al-Najah University in Nablus created confusion as they confirmed the quality and the authenticity of the products identified. The personnel of the university in question were seriously suspected of corruption (also linked financially to Al Thulathia) as the tests by the other official or private laboratories proved the medicines were counterfeit.¹⁵⁸ Even more serious: the local police saw possible collusion in this illicit trafficking by the Al Arabi Center for Cancer and Blood Diseases, a subsidiary of Al Thulathia.

The manager of the main Palestinian medicines distributor, Abu Hijleh, a former pharmacist who, up to recently, had a permanent Canadian residence permit, was very skilful in selling counterfeit medicines. He particularly talked about access to low-cost treatment in a "humanitarian" spirit (sic) compared with the Israelo-western oppressors.

This demagogic rhetoric encouraged local pharmacists to unknowingly buy counterfeit medicines at preferential prices compared with existing competitors. The cynicism of Abu Hijleh seems to be limitless since he developed a Machiavellian technique for disposing of counterfeit medicines when he was advisor at the Al Arabi Center for Cancer and Blood Diseases. In fact, Hijleh ensured that the patients were initially treated with legal medicines, waiting for the temporary improvement brought about by the medicine, then when the risk of relapse appeared, he then proposed counterfeit medicines whose harmfulness was somewhat 'diluted' by the foreseeable weakness of the patient in question. Questioned by the local security authorities, he acknowledged his links with the Jordanian network for counterfeit medicines.

According to the British researcher Roger Bate, the case is currently blocked by political protection on the Palestinian side and it is unlikely that the Palestinian hospitals will make their files available to the courts, thereby proving how real this local counterfeiters' network is.

We should lastly explain that the Chinese authorities, once warned of the links between their country and the trafficking in Jordan (2007) and in the Palestinian territories (2008), carried out raids on 11 production sites in four provinces: Guangdong, Zhejiang, Jiangsu and Henan. Links between Al Thulathia and the company Sky Park International were also revealed and the Palestinian authorities informed the Chinese authorities who afterwards prevented members of Al Thulathia from entering their territory. Arrests were also made in six criminal organisations including Sky Park International belonging to Wajee Abu Odeh, currently on the run.

- Egypt

A member of the Jordanian-Chinese network, Sherif Abdul Kareem Abu Kasheh then directed his activities towards Egypt where he established a new distribution centre more independent from the rest of the network and targeting specifically the Egyptian market, while Iraq was the priority target for counterfeiters based in Jordan and Syria.

¹⁵⁷ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 212.

¹⁵⁸ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 215.

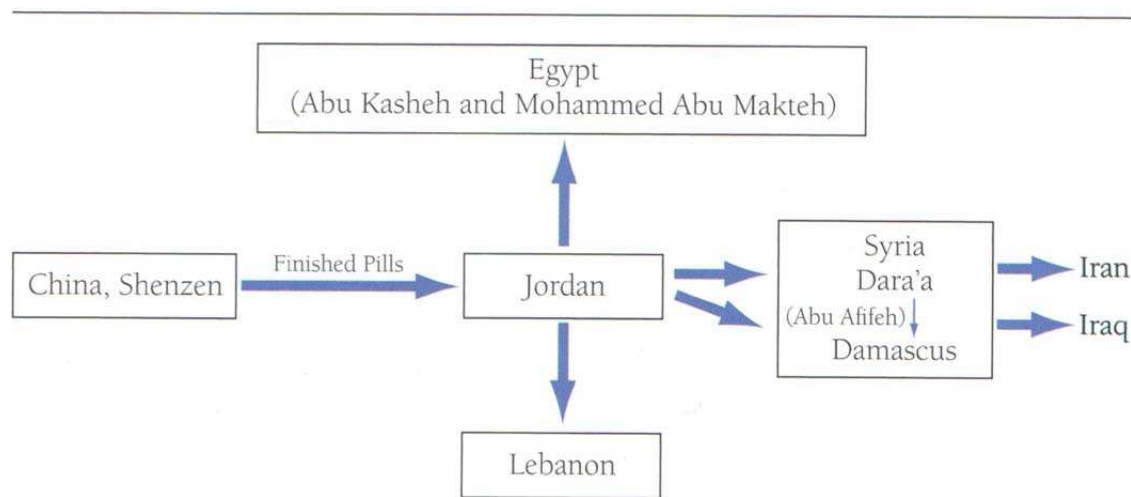


Figure 6: Summary of the distribution in the Middle East in 2007.¹⁵⁹

The Abu Kasheh network was infiltrated by the security forces through Mohammed Markieh who was the originator of the Jordanian network but who, once arrested, turned informer. Thanks to Mohamed Markieh's infiltration, Abu Kasheh, after taking six months to build up confidence, accepted to meet a potential buyer under the code name "Monaco" supposedly a buyer from the Colombian FARC (Fuerzas Armadas Revolucionarias de Colombia). Thanks to this stratagem, on April 14, 2009 the Egyptian authorities arrested Abu Kasheh in his apartment in Cairo. At the time of his arrest, the authorities seized over 5,000 boxes of counterfeit medicines for Alzheimer's disease and more than 1,700 boxes of counterfeit medicines for breast cancer. Sentenced to two years in prison, he was released in the spring of 2012 and is currently thought to be in Jordan where he has resumed his activities. In Cairo, investigations proved that the Abu Kasheh network was responsible for several deaths¹⁶⁰. The volume of counterfeited legal medicines was assessed at half the legal volume of equivalent medicines for the whole of Egypt.¹⁶¹

- Syria

After this initial 'Jordanian-Chinese', Palestinian and Egyptian stage, the criminal network then turned towards Syria to run its illegal activities more efficiently. In Damascus, activities in counterfeit medicines for the Middle East were developed with Abu Afifeh as leader, originally based in Jordan. The manufacturing equipment was imported from China and Austria. But the Syrian authorities identified distribution hubs in Aleppo, Idlib, Hims and Hamas and about a dozen people were arrested. In May 2009, numerous raids were carried out in Syria to dismantle these networks and resulted in 73 arrests. Four tonnes of stolen medicines, either not authorised for sale or counterfeit, were seized at this time, of which 60 types of counterfeit medicines from western Europe and also half a dozen counterfeit versions of medicines from local companies: Nile Pharmaceuticals and Chemical Industries Company (Egypt), Aleppo Pharmaceutical Industries (Syria) and Hikma Pharmaceuticals (Jordan). The majority of packages had fake Iraqi Ministry of Health stamps, indicating that these products were intended for sale in Iraq.

This operation proved to be a success for the Syrian regime and, according to Roger Bate, the biggest case of dismantling a counterfeit medicines network to date. But the network is still partially in existence.¹⁶²

¹⁵⁹ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 219.

¹⁶⁰ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 220.

¹⁶¹ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 220.

¹⁶² Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 222.

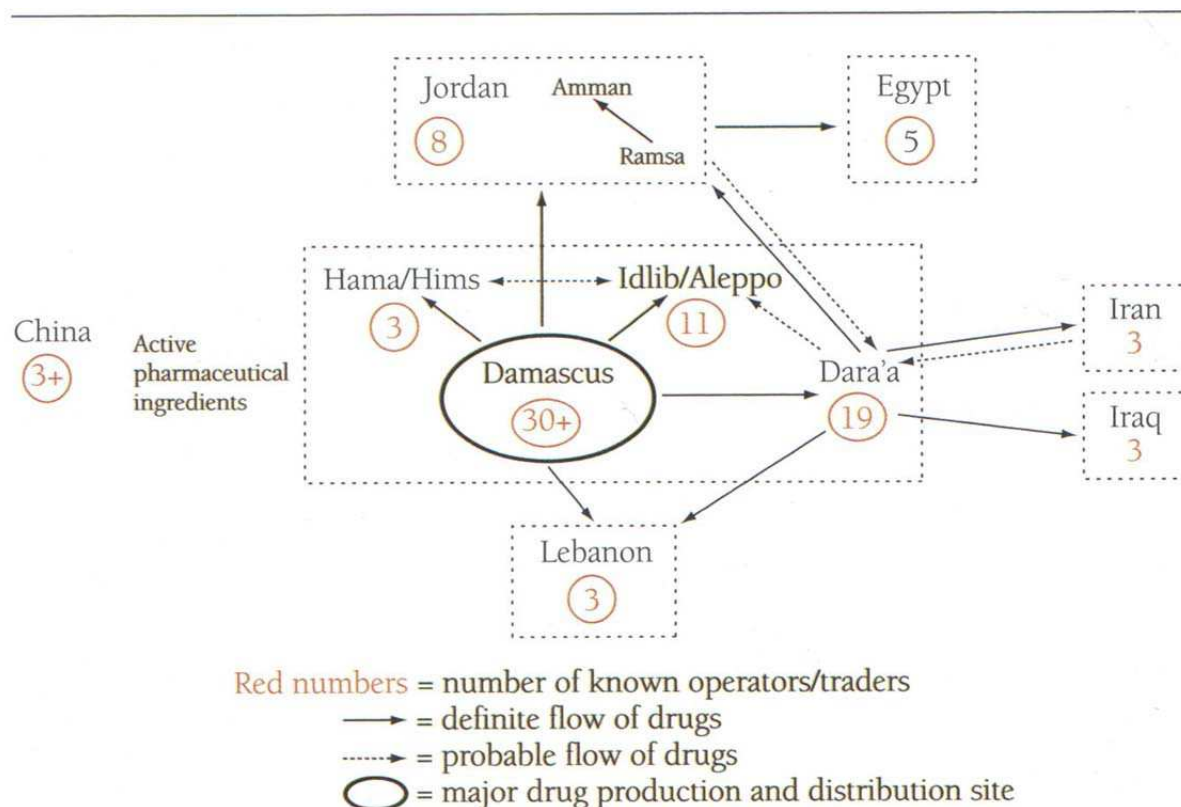


Figure 7: Distribution network in the Middle East, 2009.¹⁶³

It should be noted that for many years Syria has been a hub for counterfeit medicine trafficking and Syrian companies manufacture, import and export illicit medicines to Europe and the Middle East. According to the European Commission, 37% of the counterfeit medicines seized at the European Union borders in 2008 came from Syria.¹⁶⁴ More generally, since 2008, the Middle East has become a strategic area for counterfeit medicine trafficking with, according to certain observers, the involvement of terrorist organisations such as the Hezbollah. The Middle East's strategic position between Asia and Africa makes it a particularly sensitive area for such trafficking.¹⁶⁵

¹⁶³ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 221.

¹⁶⁴ European Commission Taxation and Customs Union, Report on EU Customs Enforcement of Intellectual Property Rights: Results at the European Border, 2008, available on http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2009_statistics_for_2008_full_report_en.pdf (access on May 2, 2012).

¹⁶⁵ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 205.

II.3.c. The 'Avastin' network

The second channel is somewhat an extension of 'Jordanian-Chinese-Syrian' network since the counterfeiters' networks then tried to export certain counterfeit medicines, particularly Avastin, to western countries probably through Turkey.



The 'Avastin'¹⁶⁶ case concerns a cancer drug which appeared at the Syrian border in 2009, that is three years before copies of the same medicine appeared on the American market. It is uncertain whether the Middle Eastern channel previously described was used as a 'corridor' or if the medicines in question were manufactured locally or both. In fact, it is difficult to trace with any certainty the 'overall path' taken by the counterfeit medicines as the counterfeit Avastin then went back and forth between Turkey and Egypt, before the products were sold to a Swiss wholesaler (Hadicon AG) then a Danish one (CareMed ApS).

The problem showed up more clearly when a British wholesaler, Richard's Pharma Ltd, bought 120 packs of counterfeit Avastin from a Turkish wholesaler and exported 38 of them to the United States. The remaining 82 packs were sold by Richard's Pharma Ltd to the British wholesaler, River East Supplies Ltd. This British company then sent the counterfeit medicines to the United States to a distributor in Tennessee.¹⁶⁷ The medicines were then bought by American doctors through a company belonging to Thomas Haughton called Montana Healthcare Solutions. Finally, it should be explained that Haughton's brother-in-law, Kris Thorkelson, a pharmacist based in Winnipeg in Canada, distributed medicines by Internet to American consumers on the website Canadrugs.com and was investigated even though it did not sell Avastin. The investigators however accepted Thomas Haughton's good faith when he stated that he did not know the nature of the counterfeit medicines he had obtained. The two British wholesalers, Richard's Pharma Ltd and River East Supplies Ltd, also proclaimed their good faith and insisted that they did not know that the medicines were counterfeit.

¹⁶⁶ Benoit Faucon, Jeanne Whalen, "Tracing Fake Avastin to the Mideast", *The Wall Street Journal*, February 24, 2012.

¹⁶⁷ Benoit Faucon, Christopher Weaver and Jeanne Whalen, "Drug Distributor is Tied to Imports of Fake Avastin", *The Wall Street Journal*, March 7, 2012.

Drug Chain

U.S. investigators are probing whether companies controlled by two Canadian businessmen shipped drugs sourced overseas to U.S. customers.

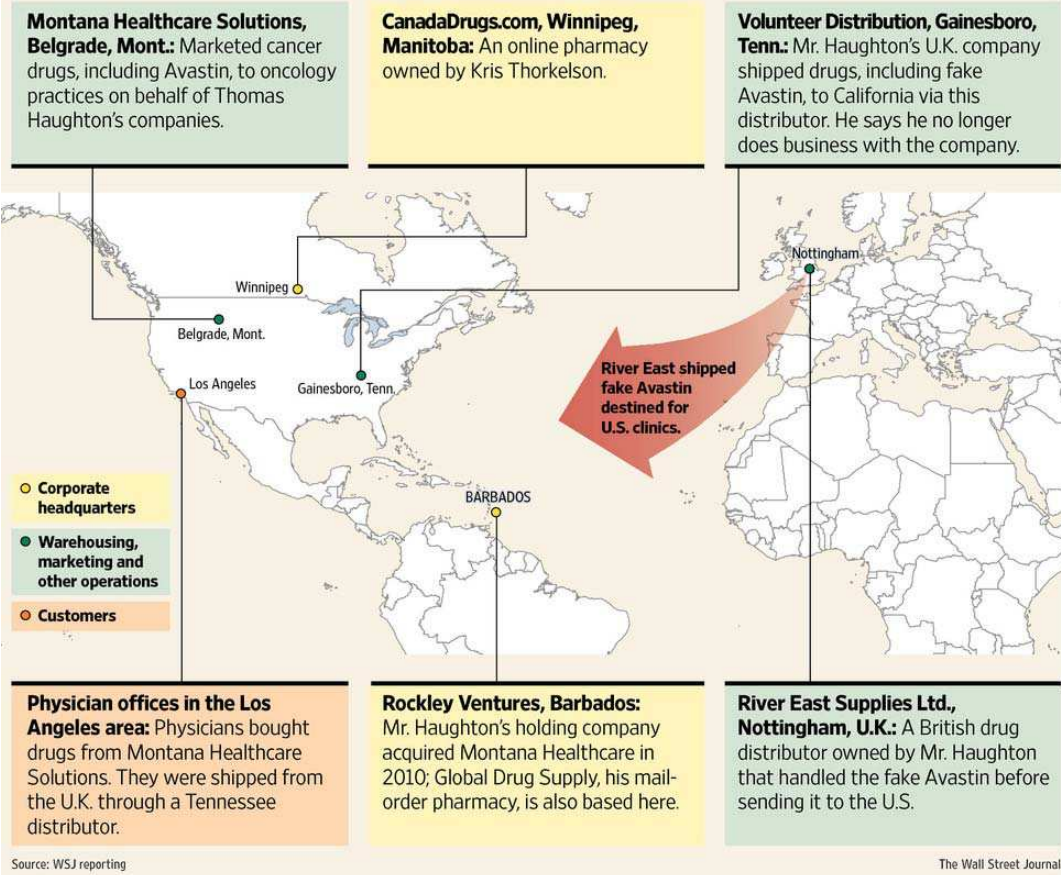


Figure 8: Diagram summarising the distribution network between the United Kingdom and North America.¹⁶⁸

¹⁶⁸ Benoit Faucon, Christopher Weaver and Jeanne Whalen, "Drug Distributor is Tied to Imports of Fake Avastin", *The Wall Street Journal*, March 7, 2012.

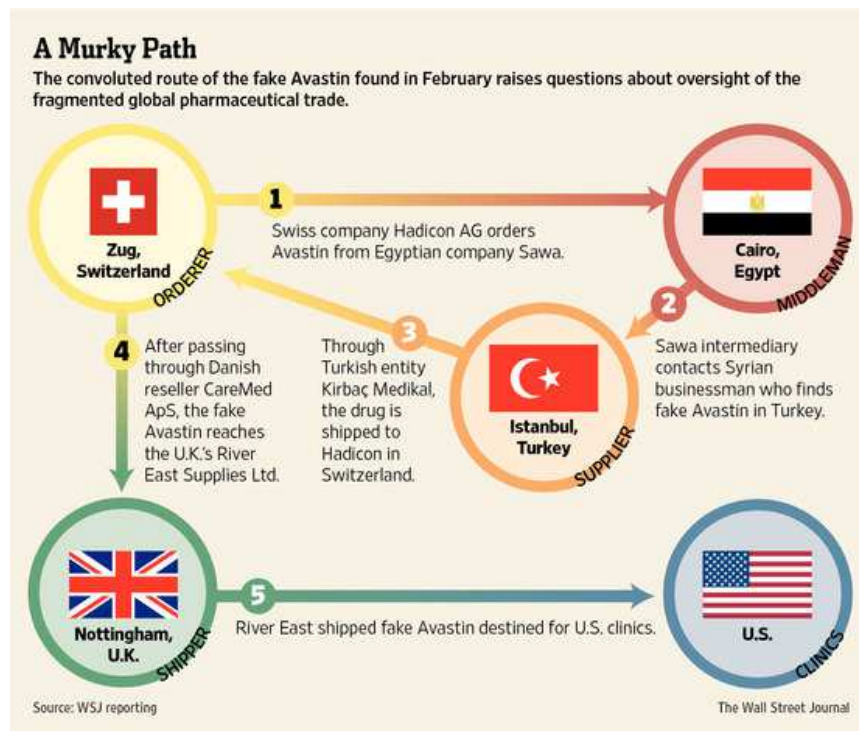


Figure 9: Diagram¹⁶⁹ summing up the overall transit route of the fake medicines in question between the Middle East, Turkey, Switzerland, the UK and the US.

This diagram starts in Switzerland: “one of the intermediaries involved in the trade, Hadicon AG in Zug, lodged an official complaint to the Public Prosecutor of the canton. Hadicon is alleged to have ordered the drug in Egypt, from a company called ‘SAWA for importing and exporting’. The merchandise is then said to have been stored in a warehouse in the free port of Zurich before being sent on to Denmark, from where the firm CareMed sent it to the UK, the last stop before the US”.¹⁷⁰

Equipment (and also bags) made in China found during the Syrian raids in 2009 suggest that there is also a Chinese network: in 2010 fake Avastin was given to 116 patients in Shanghai, some of whom suffered complications after injections in the eyes (as well as being a cancer treatment, Avastin can also be prescribed for certain eye disorders, which has been known to cause blindness).¹⁷¹

As we see from the Jordanian-Chinese network case or with ‘fake Avastin’, examining such transnational networks with any methodology is tricky to say the least, as they are by definition fragmented and polymorphous and are located in a sensitive geopolitical region. The fact that the various ‘criminal’ groups work in isolation makes it even more complicated to collect information. Finally the investigators need to assess whether or not the wholesalers or distributors involved in these affairs are acting in good faith. It is still not certain exactly where the counterfeit medicines could have been sold in Europe and the US by local distributors.

It appears however that Egypt and especially Turkey were used as relays for counterfeit medicine trafficking towards Western Europe or even the United States via the UK. The Middle East may also be a production area. So in the case of the ‘Jordanian-Chinese network’, when the Chinese production line was broken off in 2008, large-scale production shops in Damascus took over.

¹⁶⁹ Benoit Faucon, Jeanne Whalen, “Fake Avastin Took Murky Path to U.S.”, *The Wall Street Journal*, April 5, 2012.

¹⁷⁰ Peter Siegenthaler, “De faux médicaments au pays du ‘swiss made’”, *Swissinfo.ch*, 3 March 2012.
http://www.swissinfo.ch/fre/societe/De_faux_medicaments_au_pays_du_swiss_made.html?cid=32221256

¹⁷¹ Benoit Faucon, Jeanne Whalen, “Tracing Fake Avastin to the Mideast”, *The Wall Street Journal*, February 24, 2012.

The network probably comprises about 150 people and is said to be still under the surveillance of the targeted pharmaceutical companies¹⁷² particularly for high added value medicines: cancer drugs, cardiovascular disease treatments, etc.

At this stage in our study it is important to note that from Mimi Trieu to the 'Avastin' network, and including the Peter Gillespie case, the organised crime cases that we have described highlight the central role of China in this trafficking and a great variety of counterfeit medicines.

II.4. Crime in China

The Chinese authorities are concerned about the role of national organized crime in drug counterfeiting and are increasingly striving to counter organized crime. We must remember that China has the most severe sanctions in this area (the death penalty).

In this country, it is important to distinguish between crime based on exports of counterfeit drugs and crime focusing on mainland China.

II.4.a. Crime and exports from China

- The Kevin Xu case

The Kevin Xu affair is typical of the Chinese business leaders involved in counterfeiting medicines intended for clients in the West.

In July 2007 Kevin Xu, a Beijing businessman, offered potential buyers counterfeits of medicines in high demand, such as treatments for cancer, cardiac disorders or Alzheimer's disease. Xu, owner of the Orient Pacific International chemicals company, explained to his supposed clients that these medicines could be made in his factory in China and that he would have the consignments sent via different ports to conceal the origin of the products. But he had been followed since March 2007¹⁷³ and the clients in question whom he met at Suvarnabhumi airport in Bangkok and who bought USD 167,000 worth of merchandise to gain his trust, were actually special agents of ICE (US Immigration and Customs Enforcement) in the Department of Homeland Security.

At another 'business meeting' in Houston, Xu was taken for questioning by agents from ICE and the FDA.¹⁷⁴ He admitted that his production capacity could reach 200,000 boxes of medicines or over a million pills in one single consignment¹⁷⁵. At first his counterfeiting activity was more for 'lifestyle' type medicines, particularly for sexual problems, but Xu gradually expanded his range of counterfeit medicines to those with higher added value concerning treatment for heart disorders, prostate cancer or a treatment for swine flu. After the European market, Xu later targeted the US market and admitted that he was able to distribute 29 kinds of counterfeit medicines in the US.¹⁷⁶ But paradoxically Xu was also involved in legal business activities as he supplied generic medicines to Chinese hospitals. When he was arrested the Chinese authorities were of little help in identifying the business leader's counterfeit medicines.

¹⁷² Ibid.

¹⁷³ Robert Sherman, Edward Tarver, IPR Center Report, vol. 2, No. 1, March 2009.

¹⁷⁴ ICE: US Immigration and Customs Enforcement. FDA: US Food and Drug Administration.

¹⁷⁵ Dan Rather, "The Mysterious case of Kevin Xu", HDNet: Dan Rather Reports, September 14, 2010.

¹⁷⁶ Nayanah Siva, "How investigators unravelled Europe's biggest-ever-fake-medicine scam", Wired, December 2011.

At his trial in Houston in August 2008, observers realised the full extent of the affair, especially with counterfeit medicines of well-known brands intended for American consumers. Xu was sentenced to 78 months in a US Federal prison and a fine of USD 1.4 million. His arrest may have prevented the dealer from spreading counterfeit medicines within the US supply chain, but some of the counterfeit medicines destined for the UK market were distributed, as the unprecedented 'Class 1' drug alert by the MHRA was unable to prevent the partial distribution of this version in UK pharmacies and hospitals. Laboratory analyses of a medicine to treat schizophrenia showed that the counterfeit version was under-dosed as it only contained 55% to 80% of active ingredients. There are suspected links between Kevin Xu and Peter Gillespie but so far nothing has proved this hunch.

This affair shows the growing importance of the Chinese organized crime in the production of counterfeit medicines and of some initiatives by unscrupulous businessmen. Older cases in Haiti and Panama caused the deaths of dozens of children, and those mainly responsible proved to be Chinese manufacturers who were not licensed to produce medicines.¹⁷⁷ In June 1996, syrups made in China were alleged to have caused the deaths of 88 Haitian children, and in April 2007, 78 deaths were reported in Panama (219 victims in June 2011)¹⁷⁸ after taking an illicit medicine containing counterfeit glycerine¹⁷⁹. Unravelling the counterfeit networks was even trickier as in the cases of Haiti and Panama the illegal medicines passed through six and five intermediaries respectively. For Haiti, the American FDA was unable to determine the exact origin of the counterfeits in spite of the numerous investigations in China. A manufacturer named Tianhong Fine Chemicals Factory was tracked down in Dalian in northeast China but in late 1997 the factory closed down without the investigators being informed of the exact address.¹⁸⁰

In the Panama case, the perpetrators were found in the Yangtze delta thanks to the cooperation of the Chinese authorities, but there again, no manufacturers were formally charged. The manufacturer Taixing Glycerine Factory was apparently closed following investigations by the Chinese authorities at the request of the US FDA. The Chinese brokerage company involved, CNSC Fortune Way, belonging to the Chinese government, was never penalised and continues to do business today.¹⁸¹

So although there is a whole history of export of Chinese counterfeit medicines, the Kevin Xu affair shows that the distribution of this sort of product is becoming more opportunistic and cleverly marketed.

- The Sengyang Zhou case

A similar, though less widespread, affair has recently been brought to light¹⁸² concerning Sengyang Zhou, 31, from the Kunming Yunnan region. This young Chinese national specialised in the export of fake diet medicines sold on websites in 2008-2009. The products Zhou put on the market contained undisclosed active pharmaceutical ingredients like sibutramine, which can cause extreme hypertension or tachycardia. Zhou also produced counterfeits of an anti-obesity drug in China and marketed it successfully in the US. These counterfeits circulated on the Internet and particularly on online auction websites like eBay. A site specialising in the distribution of counterfeit medicines known as www.2daydietshopping.com was even based in Texas for better promotion locally. This particular site was managed by a Chinese person with US citizenship called Qingming Hu, who was followed by the American authorities.

Zhou was arrested in March 2010 in Honolulu, Hawaii during a 'business meeting' set up by FDA agents in which he confirmed that he could make large quantities of a counterfeit version of the anti-obesity medicine. In June 2011 he was sentenced to 87 months in a US federal prison for trafficking and attempted trafficking of counterfeit medicines and ordered to repay more than USD 500,000 to the victims of his crimes.

¹⁷⁷ Walt Bogdanich, "F.D.A. Tracked Poisoned Drugs, but Trail Went Cold in China", *The New York Times*, June 17, 2007.

¹⁷⁸ Source IRACM.

¹⁷⁹ Walt Bogdanich, "A Toxic Pipeline: Tracking Counterfeit Drugs", *The New York Times*, May 6, 2007.

¹⁸⁰ Source IRACM.

¹⁸¹ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 20.

¹⁸² States News Services, Chinese national sentenced to federal prison for trafficking counterfeit pharmaceutical weight loss drug, June 3, 2011.

This affair proves that criminal strategy in counterfeiting medicines also tends to rely on a diaspora settled in a targeted developed country. It shows that in spite of the complexity of the criminal system in place, various US authorities (FDA Office of Criminal Investigations, ICE Homeland Security Investigations, U.S. Postal Inspection Service) managed to work together to arrest the criminal.

But cases of Chinese counterfeiting do not target foreign markets exclusively, and mainland China is also a victim of the problem.

II.4.b. The case of mainland China

In China there is one affair¹⁸³ that reveals this ambitious criminal tendency. It began when a man named Li was questioned in July 2011 in Jinhua City, Zhejiang, during a regular taxi rank inspection. Li had in his possession 700 empty medicine bottles with their packaging and the anti-forgery tags. The police then discovered that he had been obtaining used bottles from a number of hospitals in Zhejiang for years thanks to the help of at least one person in each hospital cleaning service. This particular criminal network bought used bottles and packaging from hospital cleaning services all over China. Li's family supervised the network and supplied the bottles to medicine producers based in Beijing and Shanghai. The enquiry later revealed that Li was part of a larger network which included 300 people from all over China targeting mainly medicines for serious conditions such as cancer treatments (lymph node cancer, breast cancer and lung cancer). The counterfeit medicines were sold for CNY 10,000 per pack (USD 1,600) and even more on the Internet or in unregistered private hospitals or pharmacies.

The criminal network actually comprised four main groups¹⁸⁴: hospital cleaners who sold the packaging, the hospital agents who bought them, the wholesalers and finally the counterfeit medicine manufacturers. According to Jiang Yiqun, of the public security economic crimes investigation team in Jinhua, a cleaning agent could pocket CNY 1,500 (USD 240) for a full package of medicine to treat breast cancer (with the bottle, the instructions and the authentication labels) and CNY 1,200 (USD 190) for a medicine used to treat lymph node cancer. A drug inspection officer in the same city said that most of the medicines contained starch and wheat powder and could cause serious diseases and even death.

In November 2011, 16,000 police officers were called in, leading to the arrest of 1,770 suspects in this trafficking. Counterfeit medicines worth CNY 2 billion (USD 315 million) were seized by the Chinese authorities. The search also unearthed 1,400 counterfeit medicine production or marketing facilities.

Like the previous examples in English-speaking countries, we can also observe here – on a grander scale – the involvement of corrupt players directly linked to the health sector.

For most experts, the Chinese organized crime is unquestionably the leader in counterfeit medicines, but other countries too can be involved in this kind of trafficking, particularly India. The researcher Roger Bate reports the case of a famous Indian counterfeiter named Rajesh Sharma, also known by the name Rajesh Dua, who allows the purchasers themselves to decide on the type and content of the product to be used in the medicine. This semi-industrial counterfeiter employs some forty people for a production worth tens of millions of dollars.¹⁸⁵ What is special about China is the huge number of counterfeiters who do both legal and illegal business and who can produce large quantities of counterfeit medicines partly destined for export, so the Chinese authorities are undoubtedly a little less vigilant. As a result, a number of pharmaceutical companies are unsure of the exact origin of their production because, according to analyses by Philippe Andre, a teacher at the School of Pharmaceutical Science and Technology in Tianjin University “39% of European and US pharmaceutical companies are ill informed of the origin of the Chinese producers with whom they work”.¹⁸⁶

Certain pharmaceutical companies therefore share some responsibility for this situation.

Finally there is the difficulty in describing these Chinese counterfeiters, as situations vary enormously and information sources are limited: manufacturers who, like Kevin Xu, have both legal and illegal activities; Chinese

¹⁸³ Alice Yan, “Massive fake-drug network busted”, *SCMCOM*, November 21, 2011.

¹⁸⁴ *Ibid.*

¹⁸⁵ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 152.

¹⁸⁶ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 180.

counterfeiter networks who, as in the case of Sengyang Zhou, have foreign intermediaries; and counterfeiting cases concerning mainland China which can involve hospital networks. And there is one last case that is even more difficult to understand: what role do 'conventional' criminal organisations, like triads, play in these dealings?

II.4.c. Evolution of criminal organisations in China

In China relations between the state and crime are largely ambiguous. The Chinese criminal economy is summed up in a paradox: "On the one hand, corruption should be preserved as an element of stabilisation for the Party-State apparatus through rent seeking, but on the other hand, it should be opposed as a destabilising factor of its political legitimacy, which threatens the survival of the regime. In other words, in spite of the current political rhetoric, the fight against corruption can only be limited and used only as an example, or they risk collective suicide."¹⁸⁷

The Chinese population may be largely in favour of these criminal organisations being subjected to the authority of the Chinese government, seeing it as bringing more stability in the face of the unpredictable effects that these illegal organisations can generate within society.¹⁸⁸ But the most frequent mistake in describing these Chinese organisations is to think that they are still somehow hierarchical, whereas "under pressure from the Chinese government and market dynamics (including the black market), criminal networks are above all flexible".¹⁸⁹ On the other hand, although such organisations continue to recruit on the margins of Chinese society, they also seek possible members among politicians or well-known individuals with a strong social status.¹⁹⁰ In general, relationships between Chinese politicians and criminals are particularly widespread, especially at intermediate or lower levels and based on corruption which protects the criminals from illegal activities,¹⁹¹ particularly counterfeiting.

It was in the 1980s that contraband and counterfeiting businesses (cigarettes, weapons, currencies, medicines, etc.) really took off in China.¹⁹² According to counterfeiting expert Li Guorong, in general "counterfeiting has become so significant that taking radical action would have a disastrous effect on the economy and could destabilise the government, some of whose factories and warehouses connected to counterfeiting belong to the local army or to political leaders".¹⁹³ In the more specific case of counterfeit medicines, the Chinese government has long been somewhat tolerant towards the counterfeiters involved.¹⁹⁴

¹⁸⁷ Guilhem Fabre, "Etat, corruption et criminalisation en Chine", *Revue internationale des sciences sociales*, No. 169, March 2001.

Sometimes large-scale corruption is officially recognised. One of the most significant examples is the death sentence in May 2007 on Zheng Xiaoyu, former manager of the State Food and Drug Agency, for accepting bribes from eight pharmaceutical and medical companies and having illegally approved their products which led to dozens of deaths and undermined confidence in the Chinese health system.

¹⁸⁸ Ibid.

¹⁸⁹ Ibid.

¹⁹⁰ An Chen, "Secret societies and Organized Crime in Contemporary China", *Modern Asian Studies*, vol. 39, No. 1, 2005, p. 77-107.

¹⁹¹ Peng Wang, "The Chinese mafia: private protection in a socialist market economy", *Global Crime*, vol. 12, No. 4, 2011, p. 290-311.

¹⁹² He Bingsong, *Le crime organisé en Chine. Des triades aux mafias contemporaines*, CNRS éditions, 2012, p. 61.

¹⁹³ Quoted by Peter Navarro in "Chargers Join China's Deadly Imitations", *Asia Times Online*, August 1, 2008.

Roger Bate confirms the fact that the Chinese army does indeed host medicine counterfeiting activities.

Roger Bate, "The deadly world of fake drugs", *Foreign Policy*, No. 168, September-October 2008.

¹⁹⁴ Roger Bate, Karen Porter, "The Problems and Potential of China's Pharmaceutical Industry", *AEI online*, 23 April 2009.

In China, criminal organisations have also adapted to anti-crime campaigns and have redirected part of their assets to legal activities. In the city of Chengdu (capital of Sichuan province), a criminal organisation specialising in illicit activities in the medicine sector (theft in particular) became partly involved in legal activities by buying shares in legal pharmaceutical structures, particularly by investing in a medicine production unit and donating to medical institutions¹⁹⁵. Members of this organisation included doctors, hospital managers and primary school teachers. These criminal organisations are in fact similar to informal relationship networks. Such networks can then resume a more hierarchical structure by continuing to recruit in marginal groups and regularly approaching politicians and people with a high social status. The real leaders give their instructions 'behind the scenes' and then break with the original strategy aiming to favour legal business activities.¹⁹⁶ In this case we find ourselves facing particularly resilient networks that are able to play on 'licit' and 'illicit' activities in a pragmatic and opportunistic manner to avoid arousing too much suspicion in their environment.

This example shows the importance of corruption and illicit economic dealings that need to be identified locally. In the past few years Chinese regions have gained more independence and developed an increasingly autonomous local economy¹⁹⁷. The counterfeit medicine industry can benefit a whole series of economic sectors thanks to the organisation of the trafficking in question (restaurants, hotels, transport companies).¹⁹⁸ This regional dimension of the counterfeit medicine trade in China is even more strategic in that local court rulings find it difficult to question the 'favourable' economic context around counterfeiting.¹⁹⁹ Furthermore, investigations are made more difficult in the Chinese system of decentralised factories as in general, finding the counterfeiting factories is tantamount to finding your way through a complicated labyrinth with a multitude of intermediaries and suppliers.²⁰⁰

There is also the question of these organisations' relations with Hong Kong. Contrary to what some experts believed, Hong Kong's return to China did not lead to an exodus of triads, and a new type of alliance was set up between mainland China and the former British colony.²⁰¹ Production units of the multi-product counterfeiters in Guangdong and Fujian provinces are often financed by criminal organisations based in Hong Kong and Taiwan,²⁰² which are themselves often involved in drug trafficking, prostitution and pornography.²⁰³ In Hong Kong they have the benefit of different legislation from mainland China, which can complicate matters in logistics and in legal terms when trying to track down the originators in the counterfeiting business. The situation in Taiwan is even more favourable to criminal organisations based on the island but with illegal business activities, particularly counterfeiting, in mainland China. There is virtually no cooperation between China and Taiwan on these issues.²⁰⁴

¹⁹⁵ An Chen, "Secret societies and Organized Crime in Contemporary China", *Modern Asian Studies*, vol. 39, No. 1, 2005, p. 86.

¹⁹⁶ An Chen, "Secret societies and Organized Crime in Contemporary China", *Modern Asian Studies*, vol. 39, No. 1, 2005, p. 77-107.

¹⁹⁷ Andrew Evans, Note, "Taming the Counterfeit Dragon: The WTO, TRIPS and Chinese Amendments to Intellectual Property Laws", *The Georgia Journal of International and Comparative Law*, vol. 31, No. 3, 2003.

¹⁹⁸ Daniel C. K. Chow, declaration by, "Counterfeiting in China: Roundtable on Intellectual Property Protection as Economic Policy: Will China Ever Enforce Its IP Laws?", *Congressional Executive Commission on China*, May 16, 2005. Available on <http://www.cecc.gov/pages/roundtables/051605/index.php>

¹⁹⁹ Jessica C. Wong, "The Challenges Multinational Corporations Face in Protecting Their Well-Known Trademarks", *Brooklyn Journal of International Law*, vol. 31, No. 3, 2006.

²⁰⁰ UNODC, *The Globalization of Crime. A Transnational Organized Crime Threat Assessment*, 2010, p. 178.

²⁰¹ Mark Galeotti, "Introduction: Global Crime Today The Changing Face of Organized Crime", *Global Crime*, vol. 6, No. 1, February 2004, p. 1-7.

²⁰² Daniel C. K. Chow, "Organized crime, local protectionism, and the trade in counterfeit goods in China", *China Economic Review*, vol. 14, No. 4, 2003, p. 473-484.

²⁰³ Ibid.

²⁰⁴ Ibid.

These networks also involve the Chinese diasporas (in the US or Canada) comprising import-export companies but also community leaders, restaurant owners, and various types of employees who can help suppliers meet potential buyers.

These parasitic, opportunistic criminals seek to develop alternative strategies and invent non-conformist, flexible and undetectable organisations. Conversely, they can also implement a camouflage strategy or mimic hegemonic organisations thereby concealing their activities.²⁰⁵

To sum up the profiles of these Chinese criminal organisations involved in counterfeit medicines we propose the following classification:

- Large-scale organisations working nationally, which may be an aggregate of different types of network. We observed that in a landmark case brought to light in Jihua City “the criminal organisation” in question included different types of actor: members connected to the hospital environment, wholesalers and manufacturers of fake medicines.

- Chinese businessmen involved in legal activities who expand into illicit counterfeiting of medicines intended for export, particularly to high added value markets like North America or Western Europe. The example of Kevin Xu (p. 59) is symptomatic of local businessmen who become involved in large-scale illegal trafficking intended for international markets.

- Smaller structures which develop an Internet strategy with an intermediary abroad (Sengyang Zhou affair, p. 67).

- Small foreign structures which arrive in Chinese industrial areas and establish local companies intended to form transnational networks. The previous example of Sky Park and their relays in the Middle East is a telling example of this kind of strategy which seems to be catching on.

- And finally cross-border crime is also developing in China with foreign mafia groups who can be involved in counterfeiting medicines²⁰⁶. Chinese people living abroad seem to have an important role in these dealings with foreign countries.²⁰⁷ Access to these information sources remains tricky and tracking them down will probably require extra research work with the help of specialists in Chinese matters.

II.5. Mafia groups, terrorism and financing

What about mafia groups in the counterfeit medicine trade?

II.5.a. Mafia organisations

The Italian Mafia has a long tradition in counterfeiting, as their involvement in criminal counterfeiting organisations dates back to at least 1860 with one Giuseppe Morello, a famous counterfeiter who later emigrated to the US where he continued his activity by counterfeiting dollars (1867-1930)²⁰⁸.

²⁰⁵ Ming Xia, “Organizational Formations of Organized Crime in China: perspectives from the state, markets, and networks”, *Journal of Contemporary China*, 17: 54, 1-23, 2008.

²⁰⁶ He Bingsong, *Le crime organisé en Chine. Des triades aux mafias contemporaines*, CNRS éditions, 2012, p. 94.

²⁰⁷ He Bingsong, *Le crime organisé en Chine. Des triades aux mafias contemporaines*, CNRS éditions, 2012, p. 97.

²⁰⁸ Federico Varese, *Mafias on the Move, How Organized Crime Conquers New Territories*, Princeton University Press, 2011, p. 112.

In the more specific case of contemporary Italian mafia groups, there is hardly any doubt about the involvement of the Mafiosi in counterfeiting. Take for example the involvement of the Camorra in the luxury product industry as shown by Saviano²⁰⁹ or in the worldwide distribution of fake Bosch electric drills described by the researcher Francesco Forgione²¹⁰. These counterfeiting activities are at local level in Italy but also on a worldwide scale via specific distribution networks. Links between the Camorra and the counterfeiting business were in fact confirmed in a recent Europol report which does not reveal too much about the nature of the relations in question.²¹¹

According to certain reliable studies²¹², the Italian mafia is allegedly also directing its activities to the health sector: “the benefits for the Mafia of breaking into the medical sector is twofold: the gangs, who have now become part of the middle classes, have understood that this sector is both a guaranteed income and a means of social control.” In Calabria, forty or so private hospitals, over three hundred medical laboratory centres and doctors belong to Mafia families.²¹³ In short, the health sector plays the same strategic role for these criminal organisations as the construction sector played during the booming post-war years.

In the more specific case of counterfeit medicines, the Camorra’s involvement has been confirmed by the PSI,²¹⁴ particularly for medicines to treat infections and cardiovascular disease. Roberto Saviano²¹⁵ also mentions the case of the Camorra copying real bar codes on medicines imported into Italy via networks set up between China and the port of Naples. These counterfeit medicines are then allegedly transferred to anonymous buildings near the port to be later ‘integrated’ into the official medicine distribution network.²¹⁶

That said, in the medicine sector, links with mafia organisations are very often tricky to establish and in general it should be specified that the pattern of “integrated criminal counterfeiting remains rare and is ‘reserved’ for organisations which have full control over their socio-economic environment”.²¹⁷

But these port cities, historically mafia capitals, which no doubt guarantees them a ‘geographic income’,²¹⁸ are presumably strategic zones for direct or indirect mafia involvement in trafficking medicines. For access by sea, the western part of the Balkans is also mentioned²¹⁹ as a hub for counterfeit products from China arriving in the European Union via the Black Sea through ports on the Adriatic or Ionian Seas.

Mafia involvement in counterfeit medicines is all the more plausible, at least theoretically, because the Italian Mafia and particularly the Ndrangheta have become “entrepreneurial mafia”²²⁰ and have gone from “traditional homicides, kidnappings and large-scale drug trafficking to controlling whole sectors of the economy (such as

²⁰⁹ Roberto Saviano, *Gomorra*, dans *l'empire de la camorra*, Gallimard, 2009.

²¹⁰ Francesco Forgione, *Mafia Export*, *Comment les mafias italiennes ont colonisé le monde*, Actes Sud, 2010.

²¹¹ Europol, *EU Organised crime threat assessment*, OCTA, 2011, p. 36.

²¹² Jacques de Saint Victor, *Un pouvoir invisible. Les mafias et la société démocratique. XIX^e et XXI^e siècle*, Gallimard, 2012, p. 301.

²¹³ Jacques de Saint Victor, *Un pouvoir invisible. Les mafias et la société démocratique. XIX^e et XXI^e siècle*, Gallimard, 2012, p. 302.

²¹⁴ The information provided by Tom Kubic, PSI, about Camorra dates from 1997.

Tom Kubic, “IP Theft and International Organized Crime and Terrorism – The Emerging Threat”, IPR Center, Symposium, June 3, 2010.

²¹⁵ Roberto Saviano, *Gomorra*, dans *l'empire de la camorra*, Gallimard, 2009.

²¹⁶ European Commission Taxation and Customs Union, *Combating Counterfeit and Piracy*, 2007.
http://ec.europa.eu/taxation_customs/customs/customs_controls/counterfeit_piracy/combating/index_en.htm

²¹⁷ Bertrand Monnet, Philippe Véry, *Les nouveaux pirates de l'entreprise: Mafias et terrorisme*, CNRS éditions, 2010, p. 155.

²¹⁸ Jean-François Gayraud, *Le monde des mafias, géopolitique du crime*, Odile Jacob, 2005, p. 123.

²¹⁹ Europol, *EU Organised crime threat assessment*, OCTA, 2011, p. 35.

²²⁰ Roberto Saviano, *Le combat continue, Résister à la Mafia et à la corruption*, Robert Laffont, 2012, p. 86.

earth moving, construction, financing awarded to people in difficulty)".²²¹ The very real difficulty in analysing these mafia groups lies in the fact that "their levels and methods are much trickier to discover. It is indeed difficult to determine whether these structures are involved during production, circulation or final distribution of the counterfeit products, and whether these groups organise, do the production themselves or merely provide various services for the counterfeiters, for example ensuring the mobility of the production units. There is also a varying degree of opportunistic criminality, so the members and aims are likely to change as opportunities arise."²²²

Another probability factor is the relative proximity of the narcotics and medicine markets. Some researchers believe that the fight against drugs may have encouraged some organised criminal groups to move into the counterfeit medicine market where there is less risk of penalties and where profits remain high.²²³ The case of the Colombian drug cartels is mentioned as having certain connections with illicit medicine trafficking. In the 1990s, Cali covered their illicit dealings in cocaine, which involved purchasing raw materials, with a network of pharmacies.²²⁴ But this close link between narcotics and medicines became particularly relevant from the production angle, and as the historian Jacques de Saint Victor said in a recent work²²⁵, "Refining tons of cocaine required millions of litres of chemical precursors, made in Europe or the US. Some were widely – and freely - distributed, like potassium permanganate, but others needed permits. By investing in these pharmaceutical companies, the cartel could import all the products it wanted quite legally".

In China the involvement of triads in the synthetic drug market and particularly amphetamines is a significant and confirmed phenomenon.²²⁶ This kind of diversification could in theory lead certain organisations to move into counterfeit medicines. There are a certain number of accounts which point to this: "The corruption of government officials by local mafia groups, backed by triads, does not make things any easier. And the economic significance of the counterfeit business in some regions (between 8 and 10% of the Chinese GDP) explains the lack of enthusiasm of certain local institutions".²²⁷ But these conclusions should be treated with caution as reliable criminology studies seem rare in China or are less easily accessible than in the West.

But Europe should certainly not be excluded from these studies and some comments from specialists suggest that there may be links within the European Union between drug traffickers and counterfeit medicine traffickers or that a certain form of imitation may exist between the two networks. At an international meeting of experts in Romania, Karolyi Szep, a Hungarian customs officer declared,²²⁸ "The Balkans are a significant route for the trafficking of fake medicines, and it is the same for heroin and other drugs." One case of seizure by the Turkish police which included 6,000 fake Viagra pills and 750,000 ecstasy tablets and the wherewithal to produce 150 kilos of heroin is a good illustration of this connection.

In short, the strong presence of mafia groups in our field of study cannot be confirmed with any certainty, but we must maintain an active watch as we have discovered potential factors for the possible involvement of this kind of organisation in counterfeit medicines.

²²¹ Ibid.

²²² Barbara Pick, *Accès aux médicaments et contrefaçon pharmaceutique en Russie post-soviétique*, L'Harmattan, 2006, p. 59.

²²³ Point of view of Lewis Kontrick from the firm Reconnaissance International specialised in security problems. Source Victoria Colliver, "Bogus Drugs a Growing Threat", *San Francisco Chronicle*, August 3, 2003.

²²⁴ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 49.

²²⁵ Jacques de Saint Victor, *Un pouvoir invisible. Les mafias et la société démocratique. XIX^e et XXI^e siècle*, Gallimard, 2012, p. 257.

²²⁶ He Bingsong, *Le crime organisé en Chine. Des triades aux mafias contemporaines*, CNRS éditions, 2012, p. 38.

²²⁷ Pierre Delval, *Le Marché mondial du faux. Crimes et contrefaçons*. CNRS éditions, 2010, p.115.

²²⁸ AFP World News, *Eastern Europe confronts fake medicines trade*, October 21, 2010.

II.5.b. Terrorism

The IRA²²⁹ is the most widely cited example of a terrorist organisation involved in counterfeit medicines, particularly veterinary medicines²³⁰ to finance their activities. In the 1990s, two IRA members, Brian Ruddy and his cousin Paeder Hamill,²³¹ set up a counterfeit veterinary medicine laboratory in Hialeah Gardens, 30 miles from Miami with USD 60,000 of financial aid. The mastermind of this operation was another IRA member called Edward Davidson who was involved in the large-scale theft of British stock in May 2010. Medicine bottles were supplied by a legal company based in Atlanta on the understanding that they would be used as medical supplies during operation *Desert Storm*. One James 'Seamus' Costello was in charge of these purchases for the IRA²³². The fake labels were made on a farm in Northern Ireland belonging to Patrick Brady, Hamill's uncle²³³. The counterfeit medicines, which looked genuine to the untrained eye, contained only water, with no active ingredients, with the small difference that they were packaged in 500ml bottles, whereas the originals were sold in 100ml bottles. The counterfeit medicines were distributed by Life Services Inc., a subsidiary of a large distributor, Lextron, based in Ocala, Florida. The money obtained from these sales was then transferred to bank accounts in Northern Ireland. In March 1991 a raid on the property uncovered 30,000 labels for veterinary treatments and growth hormones.

About 700,000 animals may have received injections of the counterfeit medicine²³⁴. The affair was discovered by Merck who sued Lextron and its subsidiaries, and also Davidson and the other members of the operation in a Florida court in February 1992. Davidson was banned from selling, producing or in any way representing the counterfeit veterinary medicine and Brian Ruddy was ordered to pay USD 6 million to the company.

More recently, Hezbollah is a terrorist organisation frequently mentioned as being involved in counterfeit medicines. In March 2006, the US Terrorism Joint Force, an inter-agency initiative led by the FBI, charged 19 individuals involved in a network of counterfeit medicines to treat sexual disorders with activities in Lebanon, Canada, China, Brazil, Paraguay and the US²³⁵. Five members of this network were Canadian and according to the *Vancouver Sun*,²³⁶ which allegedly had access to the US indictment documents, a portion of the USD 500,000 per month linked to the trafficking was paid to Hezbollah.

A recent Israeli study²³⁷ confirmed that Hezbollah is focusing more and more on developing illicit activity connected with counterfeiting medicines, particularly for energy stimulants. The move to this sector may be due to the fact that drug dealing has become something of a problem for this terrorist group: the Islamic community had reservations about this kind of activity. But the fact that one of the authors of this Israeli study, Dr Boaz Ganor, is also a member of the Israeli National Committee for Homeland Security Technologies makes one wonder just how independent this sort of research is in the context of the Middle East crisis and the post-9/11 crisis.

²²⁹ IRA: Irish Republican Army.

²³⁰ Franck G. Madsen, *Transnational Organized Crime*, Routledge, 2009, p. 73.

²³¹ Case cited by Peter Lowe, "Counterfeiting: links to organised crime and terrorist funding", *Journal of Financial Crime*, vol. 13, No. 2, 2006, p. 255-257.

²³² GlobalOptions Inc., *An Analysis of Terrorist Threats to the American Medicine Supply*, Signature Book Printing, Gaithersburg, Maryland, 2003, p. 66.

²³³ Ibid.

²³⁴ GlobalOptions Inc., *An Analysis of Terrorist Threats to the American Medicine Supply*, Signature Book Printing, Gaithersburg, Maryland, 2003, p. 67.

²³⁵ Bryan A. Liang, "Safety of Drug Supply: Tougher Laws Needed to Stem Counterfeit Drug Rings", *San Diego Source The Daily Transcript*, May 4, 2006.
<http://www.sddt.com/News/article.cfm?SourceCode=20060503crd> (access March 5, 2012).

²³⁶ Kim Bolan, "For Hezbollah: Cheap Smokes, Fake Viagra", *The Vancouver Sun*, September 21, 2007.
<http://www.canada.com/vancouversun/news/story.html?id=70dfb2cd-83ff-4f0f-b6db-f49f8c8b0228> (access on March 5, 2012).

²³⁷ Roi Kais, "Hezbollah funding terror with fake medicine", *Ynetnews.com*, October 9, 2012.
<http://www.ynetnews.com/articles/0,7340,L-4279293,00.html>

In general, although a number of reports²³⁸ tend to confirm the links between terrorism and the production of medicines, particularly for ETA, the Chechens or the guerrilla groups in North Africa, there are no precise, confirmed elements to prove it. Some elements seem to argue for a close link between terrorism and counterfeiting, but as Peter Lowe²³⁹ explains, it is important to distinguish between direct links and indirect links where sympathisers provide money through a third party. Although Lowe believes the latter case is more frequent, it must be admitted that as a general rule the factual elements proving these links between terrorism and counterfeit medicines are all too often based on unsupported anecdotal elements, as a recent US report confirms.²⁴⁰ The IRA affair therefore stands alone in the detail of its *modus operandi* and independent researchers should make more effort to authenticate Hezbollah's level of involvement in the phenomenon and the possible participation of other terrorist groups in medicine counterfeiting.

But in addition to the 'mafia' and 'terrorism' issues, there is also the financial issue, and particularly money laundering in connection with counterfeit medicines.

II.5.c. Money laundering

Although, in the Middle East, counterfeiters tend to use cash to avoid being noticed in the bank systems²⁴¹, money laundering is often the focus of numerous transnational counterfeiting strategies. It was the case in the Goldfinch affair, handled by the MHRA in the UK. This affair began in 2005²⁴² with a person known by the police services for armed assault who went over into selling counterfeit medicines on the Internet and who acquired over the years a great many properties and assets. The fraud squad found it difficult to follow these laundering activities, which made light of borders and which also included the opening of an online casino with a partner in Malta.

Operation Goldfinch enabled the MHRA to find a number of bank accounts in various countries:

- Spain: three bank accounts with GBP 7 million.
- Netherlands: three bank accounts with GBP 4 million.
- Cayman Islands: one bank account with GBP 1.2 million.
- Malta: thirty bank accounts with GBP 10 million.
- Curacao: two bank accounts.
- Isle of Man: two bank accounts with GBP 3 million.
- UK: one bank account with GBP 3 million.

making a total of over GBP 28 million (USD 44 million).

And in assets:

- Two properties in London worth GBP 3 million.
- Two villas in Spain worth GBP 2.5 million.
- Two Bentleys worth GBP 250,000.

²³⁸ Wyatt Yankus, prepared for The American Council on Science and Health, *Counterfeiting drugs: coming to a pharmacy near you*, updated version, 2009, p. 2.

²³⁹ Peter Lowe, "Counterfeiting: links to organised crime and terrorist funding", *Journal of Financial Crime*, vol. 13, No. 2, 2006, p. 255-257.

²⁴⁰ National Intellectual Property Rights Coordination Center, *Intellectual Property Rights Violations: A Report on Threats to United States Interests at Home and Abroad*, November 2011, p. 42.

²⁴¹ Source: testimony from a security department manager in the medicine industry.

²⁴² Source: Mike Jones, MHRA, April 3, 2012.

- A boat in Spain worth GBP 1 million, etc.
making a total of over GBP 8 million (USD 12.5 million).

Legally, the counterfeiters have been ordered to pay damages of up to GBP 1 million.

One stratagem for stopping the counterfeiters is to prove that often they do not pay any taxes, which is a definite discrepancy, given the size of their assets and their lifestyle. In general, therefore, MHRA aims to focus on the traceability of money flows when arresting counterfeiters. This strategy may appear somewhat strange, but it is relatively effective because, of the 2,143 suspected and 179 confirmed cases of pharmaceutical crimes in 2011, six have so far led to prosecution.²⁴³ In France, in the latest report by Tracfin²⁴⁴, an organisation specialised in money laundering issues, it was shown that only two cases are linked to counterfeiting, although the report did not specify in which sectors it occurred. Finance remains a widely underestimated sector in the fight against counterfeiting, but this tool cannot become effective unless more efforts are made, not only from the law enforcement authorities, but also those who create government policies.

II.6. Cybercrime and counterfeit medicines

This section aims to describe the environment in which cybercrime is expanding in relation to the question of counterfeit medicines.

II.6.a. Cyberspace and criminality

Cyberspace is also a specific area which, to some extent, favours *deviant behaviour*.

Cyberspace seems to bring about a series of transformations in criminal behaviour.²⁴⁵

- *Globalisation*: globalisation of criminal opportunities modifies relationships between global and local as it transcends conventional borders. This globalisation also modifies these 'global – local' relations from a legal point of view.
- *Distribution networks and technologies*: these networks create new forms of commercial and emotional relationships between individuals and generate new forms of victimisation. But these information flows also make it difficult to have a coherent view of the deviant behaviour and to identify these new forms of risk.
- *The simultaneous synoptic and panoptic qualities of Internet technologies*: the assailants can observe their victims and attack them from a distance. It is also possible to identify the types of attack and the aggressors concerned.

²⁴³ Source: MHRA.

²⁴⁴ French Ministry of the Economy and Finance, *Rapport d'activité Tracfin*, 2011, p. 62.

²⁴⁵ The British university professor David S. Wall proposes a series of transformations in criminal behaviour related to the expansion of the Internet. David S. Wall, "The internet as a conduit for criminal activity" in April Pattavina (ed.), *Information Technology and the Criminal Justice System*, Sage, 2004.

- *Asymmetrical rather than symmetrical relationships*: the relationships between the aggressors and the victims also have implications for the law. For example, if there are a number of victims from different legal systems, it is difficult to finance customised legal investigations even if the criminal act is a well-known fact.

- *Long trains*: Internet enables traffic to be traced, particularly at the time of each electronic transaction by an Internet user. To some extent this is a good thing, as a copy of this data serves as a backup and supports the law, but the copies of this data are also a sensitive issue in human rights and respect for privacy.

- *Changes in the organisation of criminal activities*: for example, an isolated Internet user can carry out extremely complex criminal acts without any restrictions of time or space. These people can commit crimes which were once beyond their organisational or financial means.

These six points show that the Internet alters the way in which criminal acts are committed and the conventional interactions between aggressor and victim. Even if the nature of the offences and crimes does not change fundamentally (fraud, counterfeiting, swindling, etc.), the behaviour on this new type of network has changed considerably.

In fact from the criminal point of view, "the most significant transformation in the physical world towards cyberspace is the fact that the territory is much wider for both organisations and individuals. The criminals can operate on the Internet with less control and on a transnational scale."²⁴⁶

II.6.b. Cybercrime techniques

Four cybercrime techniques play a strategic role in the distribution of counterfeit medicines on the Internet: cybersquatting, forums, spam and search engine manipulation.

- An increase in cybersquatting

The cybercriminal technique called cybersquatting is developed to illegally obtain a domain name to mislead cyber-consumers when making purchases on the internet.

According to the internet software company MarkMonitor,²⁴⁷ cyber-squatting rocketed by over 33% in 2007 with 382,000 offences identified in the last quarter, making it the most common form of fraud.

Jérôme Sicard, Southern Europe manager of MarkMonitor explains: "In the past, cyber-squatters registered domain names to harm the brands and then sought to sell them back to them; today this is a business in itself, aimed at generating huge profits. What could be simpler to generate traffic on search engines than to use brand names in a domain name? Because most of the words in the dictionary are already used in domain names, the fraudsters and criminals are increasingly turning to brand names and trademarks". The World Intellectual Property Organisation (WIPO) has confirmed this growth in cybersquatting: since the launch of the UDRP (Uniform Domain Name Dispute Resolution Policy) in December 1999, over 17,000 disputes have been submitted to WIPO's Arbitration and Mediation Centre.

The medicine brands most often cited in these disputes²⁴⁸ include: Bayer, Eli Lilly, F. Hoffman-La Roche, Pfizer and Sanofi-Aventis.

²⁴⁶ Joan E. Foltz, "Global Crime Case: Cybercrime and Counterfeiting", *Futurist*, November 1, 2008.

²⁴⁷ MarkMonitor, Brandjacking Index, 2007. The final analysis is based on approximately 134 million recordings and 60 million email phishing attempts in nine sectors of activity: automobile, clothing, multimedia, consumer goods, electronics for the general public, pharmaceuticals, agribusiness, high technology and finance.

Source: Philippe Collier, "Les attaques contre les marques font rage sur Internet", *Contrefaçon Riposte*, March 25, 2008.

²⁴⁸ Ibid.

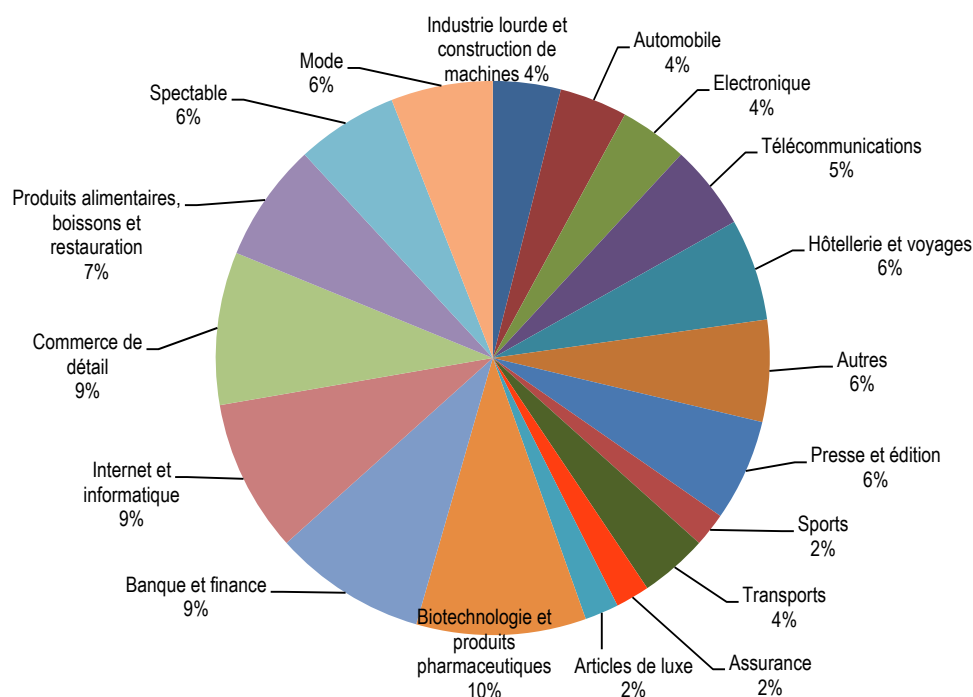


Figure 10: Sectors most affected by cybersquatting

Source: Philippe Collier, "En 2009, L'OMPI a traité 2107 plaintes de cybersquatting", *Contrefaçon Riposte*, March 23, 2010.

- Forums: strategic discussion areas

Forums are strategic in spreading information about the trafficking of counterfeit products.

Two main types of forum can be distinguished:

- Consumer forums where information is shared on products, prices and low-cost web sites. Cybercriminals target these forums by spam and fake comments to attract potential purchasers to their websites.

- More "underground" forums²⁴⁹ for amateur or more experienced cybercriminals sharing the latest innovations or proposing collaborations for illicit operations. There is a hierarchy between the members of these forums and it is easy to distinguish between the administrators, moderators, sellers, recognised members and guests who might arouse suspicion about possible undercover operations. Interestingly, these types of forum are used as meeting places between 'virtual' and 'real-world' criminal activities. These forums reduce the time factor by allocating a precise task to each cybercriminal to diminish the extent of each offence but also the risk factor by allocating cybercriminal actions to different geographic areas and protecting themselves against any possible legal proceedings.

- Spam: a vector for cybercrime

²⁴⁹ Example cited by CEIS, Study under the direction of Guillaume Tissier, *Les marchés noirs de la cybercriminalité*, June 2011, p.14.

Spams²⁵⁰ are an essential vector that use e-mail to advertise websites distributing counterfeit products. The complexity of the digital and financial flows is summed up in figure 11.²⁵¹ The pharmaceutical sector is prioritized as a target. One can see how a potential purchaser clicking on an e-mail spam will obtain - via servers based in China or Brazil - counterfeit Viagra traced back to Russia for a product manufactured in India and with a final payment to a bank in Azerbaijan.

Studies have proved that 95% of the payments for this spam were made through three banks located in Azerbaijan, Denmark and Nevis in the Caribbean. Most of the time, these bank transactions were not necessarily fraudulent in that the consumers received their orders, however both the patients and the pharmaceutical companies were taken advantage of in that these products were illegal.

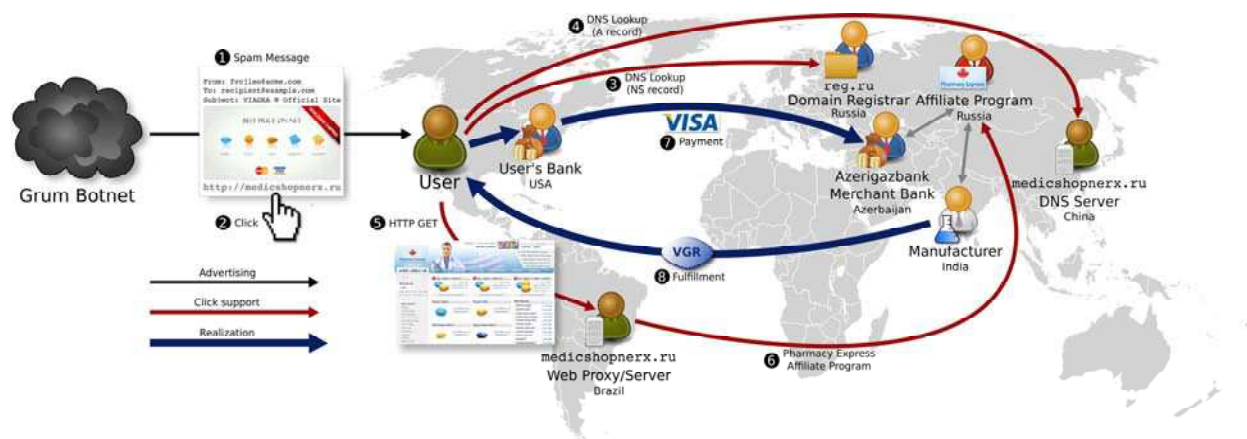


Figure 11: Digital and financial flows connected to the spreading of spam for counterfeit Viagra. Source: Neha Chevra et al., "Click Trajectories: End-to-End Analysis of the Spam Value Chain", In *Proceedings of the IEEE Symposium and Security and Privacy*, Oakland, CA, May 2011, pages 431–446.

Cybercriminals use several effective and opportunistic techniques to flood in-boxes through dedicated servers offering services for sending spam, particularly with a view to inviting the recipient to log on to attractive sites from a visual and a financial point of view. The list of recipients can also be 'targeted' thanks to the use of marketing databases.

According to Stefan Savage,²⁵² an IT expert at the University of California in San Diego who took part in this test study, there are a great many techniques for sending spam to people thanks to the internet setup without being blocked, and the real weak point is the banks. "The question is whether this problem is sufficiently strategic for politicians to become deeply enough involved." According to this study, only 0.0001% of spams are thought to result in the sale of counterfeit medicines but with a substantial gain. It has to be pointed out that spams are also used to disseminate malware such as a 'Trojan horse', which surreptitiously runs a programme in the user's

²⁵⁰ Spamming can be defined as the excessive use of an email system intended to expose, deliberately and usually repeatedly, all or some of its users to messages or content that they neither need nor have asked for, often by making sure they can be confused with the messages or content usually exchanged or looked for by these users.

Source: http://www.futura-sciences.com/fr/definition/t/internet-2/d/spam_1650/

²⁵¹ Neha Chevra et al., "Click Trajectories: End-to-End Analysis of the Spam Value Chain", In *Proceedings of the IEEE Symposium and Security and Privacy*, Oakland, CA, May 2011, p. 431-446. Graphic: Courtesy of Stefan Savage.

²⁵² David Talbot, "Anatomy of a Spam Viagra Purchase", *Technology Review*, May 20, 2011.

computer to obtain confidential information that the hackers will sell to third parties.²⁵³ These spams account for 5% of all mailing activities.²⁵⁴

A recent study²⁵⁵ revealed that most of this spam is based on an advertising approach consisting in encouraging potential clients to buy the products. Only 38% of the medicines in question are products for sexual problems, and the variety of medicines on offer is therefore much wider, with 289 different products listed, including treatments for cancer, leukaemia or diabetes.²⁵⁶ Western countries, the US in particular, are the main buyers through spam and monthly orders²⁵⁷ for the seven leading illicit medicine distributors have been estimated at more than 80,000 units.

Spam is also spread by clever cybercriminals. One of the most significant examples is the case of Oleg Y. Nikolaenko, 24, nicknamed the King of Spam, who was arrested in Las Vegas by the US authorities in November 2010. Under the name of 'Docent' he earned hundreds of thousands of dollars using his 'Mega D' botnet²⁵⁸ capable of sending 10 billion unsolicited emails a day²⁵⁹. The US Department of Justice accused Nikolaenko of spamming on behalf of Lance Atkinson and other members of the Affking group, an affiliation programme of illegal online pharmacies.²⁶⁰ According to the journalist Brian Krebs, 'Docent' also sent spam for other illegal online pharmacy networks and recordings made of SpamIt without their knowledge revealed that 'Docent' earned commissions of USD 320,000 between 2007 and 2010 to use spam to promote illegal pharmacies affiliated with SpamIt distributing counterfeit medicines. The young Russian fiercely negotiated his commissions at 45-50% because of his extremely powerful botnet, whereas normally they are 30% for a spammer.

However the importance of spam should be put into perspective, as for some researchers in cybersafety, the search engines also play a major role in the access to counterfeit medicines on the Internet.

- Manipulating search engines

According to a study directed by Nicolas Christin²⁶¹, associate director of the Information Networking Institute in Carnegie Mellon University, a quarter of the ten most frequent requests on search engines are directed to illicit pharmacies. This investigation²⁶² led by some of the foremost researchers (Carnegie Mellon, Harvard) suggests that illegal pharmacies seek to manipulate the search engines to promote their activities, especially as it is very efficient in encouraging people to buy. The researchers pointed out that the rate of conversion into a medicine purchase could be estimated at between 0.3% and 3% when search engines were manipulated, which is a much higher percentage than the previous example for spams targeting medicines (0.0001%). To aggravate matters,

²⁵³ John Richard Castronova, "Operation Cyber Chase and Other Agency Efforts to Control Internet Drug Trafficking, "The 'Virtual' Enforcement Initiative is Virtually Useless", *Journal of Legal Medicine*, vol. 27, No. 2, 2006.

²⁵⁴ Economist.com, "Long life spam. The changing landscape of online fraud", *The Economist*, November 20, 2010.

²⁵⁵ Chris Kanich, Tristan Halvorson et al., "Show me the Money, Characterizing Spam-advertised Revenue", *USENIX Security Symposium*, 2011, San Francisco, USA.

²⁵⁶ Ibid.

²⁵⁷ Ibid.

²⁵⁸ A botnet is a set of Internet connected or semi-automatic programs which interact with computer servers. Nowadays, the term is often used to designate a network of zombie computers, i.e. malicious computers. Source: Wikipedia September 2012.

²⁵⁹ Brian Krebs, "Chat With Accused 'Mega-D' Botnet Owner?", *KrebsOnSecurity*, December 5, 2011.

²⁶⁰ Ibid.

²⁶¹ Medical Daily Reporter, "Illegal Online Pharmacies Exploiting the Web", August 17, 2011.
<http://www.medicaldaily.com/news/20110817/7040/illegal-online-pharmacy-illegal-drugs-online-drug-perscriptions-online-order-of-perscriptions-il.htm>

²⁶² Study source: Nicolas Christin, Nektarios Leontiadis, Tyler Moore, "Measuring and Analyzing Search-Redirection Attacks in the Illicit Online Prescription Drug Trade", *20th USENIX Security Symposium San Francisco*, August 8-12, 2011.

the legal online pharmacies have little visibility because of this aggressive strategy of the counterfeiters on the Internet who boost their visibility on search engines by latching on to websites with .edu suffixes to make their strategy even more effective. Online advertisements can also be very efficient for directing to illicit pharmacy websites. As we can see from this study, search engine manipulation is a major problem and is no doubt vastly underestimated.

One well-known case showing the role of search engines in promoting illicit websites concerns Google and its system of keywords managed by its advertising sales division. This system, called Adwords, uses keywords to bring up an advertisement in the margin of the results page in an Internet search, if these words correspond to the words used in the request. These advertisements comprise the URL of the advertiser's website. The advertiser can reserve a keyword of a registered brand that he does not own, and this is what causes problems, particularly as in the past few years, Google has been facing lawsuits for counterfeiting from brand owners. The ambiguity of this issue comes from the fact that search engines earn most of their revenue from advertising. The online pharmacy market represents USD 1 billion a year according to market survey company eMarketer²⁶³. According to the company LegitScript LLC more than 80% of online pharmacies advertising on these search engines are illegal.

To try to counteract this visibility for websites distributing counterfeit products, some big companies have started legal proceedings against the US search engine.

These court rulings increasingly encourage the two parties (manufacturers and Google) to cooperate. They show the limits of the fight against counterfeiting, which should above all contribute to controlling the information networks.

But Google is not the only strategic search engine; there is also Bing created by Microsoft which has been the subject of a report by Legitscript and Knujon,²⁶⁴ which suggests that 89.7% of advertisements for online pharmacies sponsored by Microsoft are illicit and although Microsoft's promotional policy implies that these websites are based in the US or Canada, some websites were obviously based in a foreign country, particularly India. Finally, most advertisements for pharmacy websites presented by Bing are for medicines not requiring prescriptions. The keyword auctioning system on which Microsoft's online advertising is based is thought to be more beneficial financially to the illicit pharmacies than the legal ones.

Among the examples mentioned and deciphered by Legitscript as pharmacies sponsored by Microsoft links is the network Choice-Rx.com which says it is based in the Seychelles, but is actually part of a network known as medstore.biz, which works through an affiliation system. This system allegedly belongs to a Russian criminal organisation called Regtime, which plays an important part in the illegal pharmacy network. Legitscript believes that criminal organisations are widespread, as the criminal organisation 33 Drugs is said to own the dailymedrx.com network which advertises on Bing and is said to have a network of about a hundred affiliated pharmacy websites which sell counterfeit medicines without prescriptions. Canada has also been a major point of contention and Google was sued by the US Department of Justice for having allowed Canadian pharmacies to buy advertisements on Google Adwords that illegally targeted US consumers. That said, in August 2011 the US Department of Justice published a statement announcing an agreement with Google for the payment of a fine of USD 500 million by the company for having allowed Canadian cyberpharmacies to publish advertisements targeting US consumers and then export prescription medicines to the US in violation of the nation's laws. This fine represents the total sum of gross advertising revenue received by the company and the estimated gross income collected by Canadian cyberpharmacies from sales made in the US.

The size of the fine is evidently meant to encourage Google to exert more control over the use of its Adwords platform.

²⁶³ Thomas Catan, Amir Efrati, "Google Was Warned On Rogue Pharmacy Ads", *The Wall Street Journal*, May 20, 2011.

²⁶⁴ Knujon and Legitscript, No Prescription Required: Bing.com Prescription Drug ads, August 4, 2009.

Why not use filtering to counter the promotion of illicit websites connected with counterfeit medicines?

According to the European Alliance for Access to Safe Medicines (EAASM)²⁶⁵ one solution would be for the most frequently used search engines to ignore web pages giving information on counterfeit medicines. Such an initiative was conducted in 2009 by Google, Yahoo and Bing, which banned fake online pharmacies from using registered brands for medicine prescriptions. But these cybercriminals then switched to other methods. They now try to reach consumers by using spamming techniques on forums which appear in search engine searches (see figure 12 below: a Google search for the psychostimulant Adderall)²⁶⁶

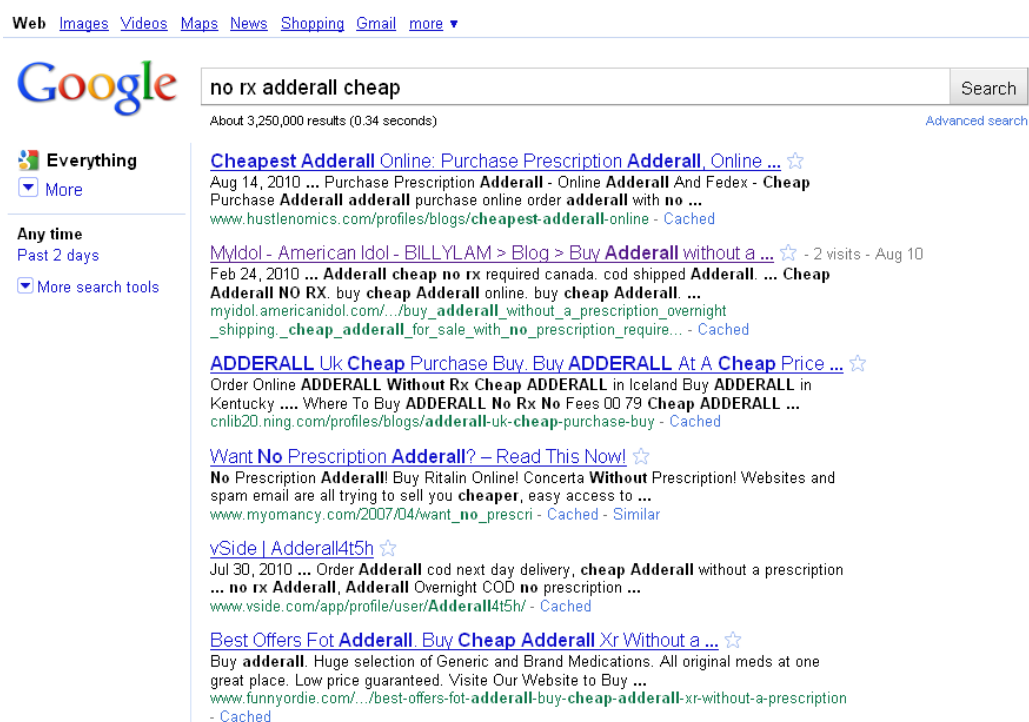


Figure 12: Search for the psychostimulant Adderall, Google page.
Source: OpSec Security, *Risk Assessment: Counterfeit Pharmaceuticals on the Online Marketplace*, Study, November 15, 2010.

Therefore, the filtering technique has its limits and it also raises civil liberty issues, as some associations have pointed out (for example La Quadrature du Net,²⁶⁷ which is very active in European institutions).

On the other hand, these problems are arising on an international level. Counterfeiting activities involve many operators and many countries. According to International Law the States are still the ultimate reference – thanks to the Treaty of Westphalia! In such a context, how can governments adopt national laws that are comprehensive, modern and compatible with those in other countries? Not to mention develop international judicial cooperation?

There is also the question of filtering and 'criminal organisations'.

²⁶⁵ Philippe Collier, "62% des médicaments vendus sur Internet sont des faux", *Contrefaçon Riposte*, July 22, 2008.

²⁶⁶ OpSec Security, *Risk Assessment: Counterfeit Pharmaceuticals on the Online Marketplace*, Study, November 15, 2010.

²⁶⁷ <http://www.laquadrature.net>

Faced with these “increasingly industrialised and hyper-reactive networks”²⁶⁸, the effectiveness of the current measures should be put into perspective. According to David Fernyhough²⁶⁹, an expert in counterfeiting with Hills & Associates (a risk management company based in Hong Kong), “The problem has simply become so huge that no measures can possibly stop it.” In the ‘real’ world but also on the Internet.

- Cybercriminal techniques with two strategic targets

Finally it is important to note that the targets of these various cybercrime techniques are either the end clients or the distribution channels.²⁷⁰

In the case of end clients, they may be attracted by an affordable price that comes from a continual flow of spam in their inboxes. A potential buyer will then start to surf the web, especially on websites that look legal. For websites selling medicines, there will generally be a statement that the online pharmacy is authorised and registered in compliance with the legislation. All these factors aim to reassure potential buyers even if they do not have a doctor’s prescription. There are a number of online pharmacies that do not require a prescription to conclude the transaction.

In the second case, the counterfeiters tend to break into the distribution channel by using Internet as a marketing vehicle, exploiting the fact that some distributors look for low-cost products to maximise their profits without thinking to check the integrity of the supply source. Once the products have been bought by the distributors, the medicines are for example marketed as legitimate products and it will then be difficult to trace their origin.

According to the UK’s MHRA²⁷¹ criminals have for some years now preferred to distribute counterfeit medicines to pharmacy wholesalers, particularly those supplying to hospitals or medical support organisations rather than directly to consumers. By targeting these organisations, the counterfeiters can capture a bigger, more lucrative market. For example, in the UK, the wholesale value of a pack of twenty-eight pills of medicines to treat prostate cancer is USD 260, which can give the traffickers a comfortable profitable.²⁷²

But with all these various cybercrime techniques, we should not lose sight of the fact that the principal distribution vector of counterfeit medicines for end consumers remains the illicit online pharmacies.

II.6.c. Online pharmacies

What types of pharmacies can be found on line?

In the eyes of the law, there are three types of online pharmacy²⁷³:

- Some countries authorise online pharmacies to deliver medicines to patients after obtaining an electronic prescription delivered by a doctor.
- Online pharmacies circumvent the law by employing doctors who prescribe medicines on the basis of information supplied by the patients in an online questionnaire. Once the medicines have been prescribed, they are sent to the patients.

²⁶⁸ afp.com, Internet news, “Statement by Christine Huber, counterfeit project manager at Sanofi-Aventis”, *AFP*, June 23, 2008.

²⁶⁹ Donald G. McNeil Jr, “In the World of Life-Saving Drugs, a Growing Epidemic of Deadly Fakes”, *The New York Times*, February 20, 2007.

²⁷⁰ UNICRI, Counterfeiting, *A Global Spread, A Global Threat*, 2007, p. 90.

²⁷¹ Roger Bate, *Phake: The Deadly World of Fake Drugs*, Appendix, The AEI Press, February 2012.

²⁷² The Sunday Times, *Factory for Fake Prescription Drugs*, September 23, 2007.

²⁷³ IRACM, Fiche La falsification sur Internet, January 30, 2012.

- The most illegal pharmacies deliver all kinds of medicine anywhere in the world, including those that require a prescription, with no controls at all, provided the patient can pay for them.

In Europe the situation can be summed up as follows:

- Online sale authorised in primary care for medicines for which a medical prescription is optional: Ireland, Spain, Belgium, Italy, Poland, Czech Republic, Slovakia, Hungary, Finland.
- Online sale authorised for all medicines if the site is connected to an actual pharmacy: Germany, Denmark, Portugal, Sweden.
- Online sale authorised for all medicines: UK, Netherlands.
- Medicine only sold on prescription: Switzerland.
- These Internet sales were recently authorised in France on certain conditions.²⁷⁴ Firstly, the website must be owned by a chemist with a dispensary: to put it plainly, sales of the medicine remain the domain of the professionals in the sector and should be an additional activity. No 'pure-player' from the web can break into this market. Next, the website must be approved by the Regional Health Authority. The owner of the site must also register it with the Order of Pharmacists. Finally, online sales are currently limited to OTC (over-the-counter) medicines, i.e. those that can be bought freely and that customers can pick up off the shelves themselves.

In general, the free circulation of merchandise between member States is one of the principles of the European Union. In virtue of this principle and since the voting of a jurisprudence in the European Court of Justice in 2003 (known as 'DocMorris'), Europe considers that a State cannot ban pharmacies from selling over-the-counter medicines online.²⁷⁵ The situation is therefore likely to change again in the short or medium term in France.

In the US online selling is allowed for all medicines but as we will see, the online standardisation systems are not sufficiently well established.

A recent study conducted by MarkMonitor²⁷⁶ revealed a strong interest from consumers for websites offering pirated content and counterfeit products. Over 53 billion visits have been registered in one year. Of these, counterfeit medicines attract over 92 million visitors annually. Three-quarters of the sites suspected of hosting content listed as 'counterfeit' are located in North America or in Western Europe according to a MarkMonitor study conducted for the US Chamber of Commerce.

The problem is increasing: an enquiry²⁷⁷ led jointly by Interpol and the WHO four years ago, with the help of 24 countries, referenced 800 illegal sites, 125 of which are thought to be located in France.

²⁷⁴ Christophe Guillemin, "Polémique: la vente de médicaments en ligne désormais autorisée", Usine Nouvelle, December 24, 2012.

<http://www.usinenouvelle.com/article/polemique-la-vente-de-medicaments-en-ligne-desormais-autorisee.N188556>

²⁷⁵ Ibid.

²⁷⁶ Sécurité Informatique, "Selon Markmonitor le piratage et la contrefaçon sur Internet dépasseraient les ... 200 M\$ chaque année", *Sécurité Informatique, Cybercriminalité*, No. 344, Monday January 24, 2011, p. 5.

²⁷⁷ Mutualité Française, Faux médicaments sur Internet: des contrefaçons dangereuses pour la santé, November 20, 2009.

A number of elements provided by MarkMonitor show that this trend is worsening²⁷⁸:

- The VIPPS²⁷⁹ programme led by the NABP (National Association of Boards of Pharmacy) has certified only four online pharmacies out of the nearly 3,000 listed in this study. This trend was confirmed in a more recent study in July 2012 with 96.71% of online pharmacies practising illegally.
- These websites receive tens of thousands of visitors a day, to the extent that their activities are sufficient to earn them a listing in Alexa, the reference site for internet statistics.
- China heads the list (49%), followed by India (17%) for those countries of origin of the products according to the advertisements.
- The discounts (up to 90%) are significant of the fraudulent origin of these medicines.

In 2008, the National Center on Addiction and Substance Abuse at Columbia University²⁸⁰ which researches the phenomenon in the US, identified 365 websites offering medicines on line that in principle required a prescription: 85% of these sites did not ask for the prescription and only two of them were officially registered as online pharmacies. More recently, the company OpSec Security²⁸¹, published a study which estimated the number of non-accredited pharmacies not requiring a medical prescription as 89% versus 51% in 2007.

This study provides other significant results:

- Discounts on medicines reach 40% or more on 86% of non-accredited online pharmacies.
- The illicit activities of these non-accredited pharmacies are in full growth.
- Three-quarters of these pharmacies describe certain products still protected under a US patent as generic medicines. These medicines are often made in India and are still not authorised for sale in the US.
- Marketing techniques²⁸² to target consumers are increasingly sophisticated and can cleverly divert any risk of interception by the authorities. The counterfeiters target message forums with spams to avoid the new improved filters used by search engines to detect illicit pharmaceutical sites.
- consumers are at an increasing risk of reaching non-accredited sites that pass themselves off as legitimate sites, according to OpSec Security.

Other studies have made it possible to gather a certain number of analyses to get a better grasp of distribution. Many e-pharmacies with illicit activities are taking on an increasingly sophisticated legitimate appearance in targeting consumers and using advanced marketing techniques.²⁸³ One technique consists in the site passing itself off as being in a 'secure' country. One in five online pharmacy sites claims to be Canadian but is registered in Russia, Panama or Bulgaria, which are high-risk countries for counterfeiting problems. Another strategy that counterfeiters privilege is the 'merchandising' of 'star' medicines on the internet before their official launch. For example, the European Commission reported that one counterfeit obesity medicine and smoking cessation

²⁷⁸ MarkMonitor, Press Release, *MarkMonitor Finds Online Drug Brand Abuse is Growing*, September 28, 2009.
<https://www.markmonitor.com/pressreleases/2009/pr090928-bji.php>

²⁷⁹ VIPPS: Verified Internet Pharmacy Practice Sites. VIPPS is an American accreditation programme of the National Association of Boards of Pharmacy which aims to provide official certification for legal online pharmacy websites.

²⁸⁰ The National Center on Addiction and Substance Abuse at Columbia University, "You've Got Drugs! V: Prescription Drug Pushers on the Internet", *A CASA White Paper*, July 2008.

²⁸¹ OpSec Security, Press release, *OpSec Security Identifies Latest Market Trends in the Online Sales of Prescription Drugs by Internet Pharmacies and Trade Boards*, December 10, 2010.

²⁸² Businesswire.com, "OpSec Security Exposes Emerging Schemes by Rogues Internet Pharmacies to Target Consumers", *Business Wire*, December 7, 2010.

²⁸³ Ibid.

product was “on sale on several websites” before its approval. Sanofi, which developed this future blockbuster, has filed a number of suits against counterfeiters since 2004 with the WIPO’s Arbitration and Mediation Centre²⁸⁴.

The latest Brandjacking Index report of 2009 from MarkMonitor highlights an alarming increase in the counterfeiting of well-known pharmaceutical brands. Asian manufacturers are offering counterfeits of brand medicines on B2B trading platforms that are normally delivered on prescription. These online pharmacies have increased their presence on the market. Their turnover was estimated at USD 11 billion in 2009 (USD 4 bn in 2007).

- Difficult traceability

In spite of the difficulty in tracing the origin of certain medicines, there is some geographic information about illicit pharmacies and on the origin of the spams used to sell counterfeit medicines (see figure 13 below).²⁸⁵ The United States are the champions in hosting illicit online pharmacies, with 36% of the total in 2009 versus 49% in 2008.

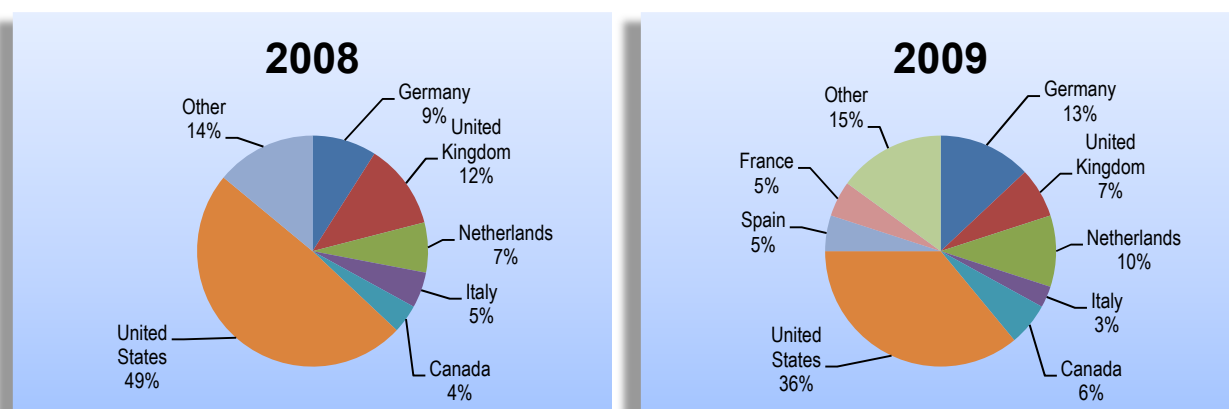


Figure 13: Origin of spam aimed at selling counterfeit medicines.²⁸⁶

Chinese organized crime has specialized somewhat in selling counterfeit medicines. Most of the spam attracting people to these rogue sites comes from China (31% in 2009, see figure 14)²⁸⁷. In addition, it can be noted that the pharmaceutical sector accounts for 64% of all²⁸⁸ (the second industrial sector is watchmakers, with 6.5%), which shows just how strategic this sector is for counterfeiters.

²⁸⁴ Sandrine Cabut, “Une pilule anti-obésité pullule sur l’Internet”, *Libération*, March 29, 2006.

²⁸⁵ MarkMonitor, *Brandjacking Index*, summer 2009.

²⁸⁶ Ibid.

²⁸⁷ This 2009 statistic should be taken in perspective, as in 2010, the results of the company Sophos placed China in fifteenth place among spam-relaying nations. Sophos study conducted between January and March 2010. Source: Presswire.com, “Dirty dozen spam- relaying countries revealed by Sophos; China dramatically disappears from list of worse spam-relaying nations for the first time”, M2 Presswire, April 28, 2010.

²⁸⁸ Message Labs, *State of Spam Report*, 2010.

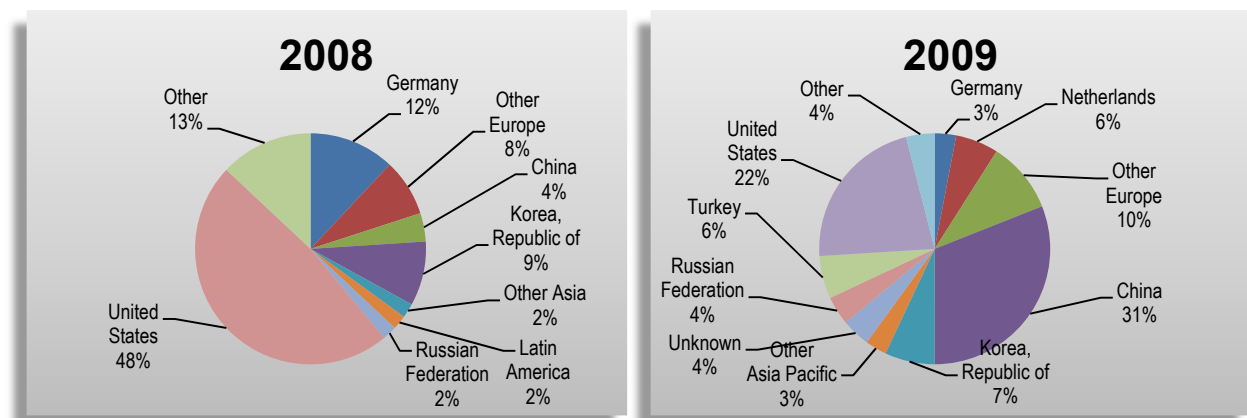


Figure 14: Origin of spam leading to rogue websites.²⁸⁹

II.6.d. Concrete cases to illustrate the ‘cybercrime – counterfeit medicine’ combination

We focus particularly on health scares which can be opportunities for cybercrime strategies, and also a large-scale Russian example that brought to light counterfeit medicine networks organised on the Internet.

- Health scares

Europol²⁹⁰ is concerned about the considerable role played by the internet in aiding criminal organizations to distribute counterfeit medicines. According to this international organization, these criminal groups are well structured and able to instrument health scare situations. That was the case with the swine flu virus during which there was an increase in the trafficking of counterfeit medicines supposed to treat the virus. In circumstances like this, opportunistic cybercriminals²⁹¹ send messages (see some examples of Russian cybercriminal messages below) to boost sales of counterfeit medicines like Tamiflu and manipulate the search engines during epidemics that require emergency treatment.

According to the company Sophos, Russian cybercriminals targeted UK citizens during the swine flu crisis as there were limited stocks available locally.²⁹² In July 2009 when there were concerns about whether the UK pharmaceutical industry could supply enough Tamiflu, searches on the Internet for this medicine in the UK increased by 1,400%²⁹³ and Internet users were often directed to websites managed by cybercriminals (see figure 15).

²⁸⁹ MarkMonitor, Brandjacking Index, summer 2009.

²⁹⁰ Europol, *EU Organised crime assessment*, OCTA, 2011, p. 34.

²⁹¹ Graham Cluley, “Swine flu fears making millionaires out of Russian hackers, Naked Security Blog”, *Sophos*, November 16, 2009.
<http://nakedsecurity.sophos.com/2009/11/16/swine-flu-fears-making-millionaires-russian-hackers/>

²⁹² Sharma Rasik, “Russian Crime Gangs Selling Fake Tamiflu Online”, *Top News*, November 16, 2009,
<http://topnews.co.uk/2728-russian-crime-gangs-selling-fake-tamiflu-online> (accessed on April 27, 2012).

²⁹³ Graham Cluley, “Swine flu fears making millionaires out of Russian hackers, Naked Security Blog”, *Sophos*, November 16, 2009.

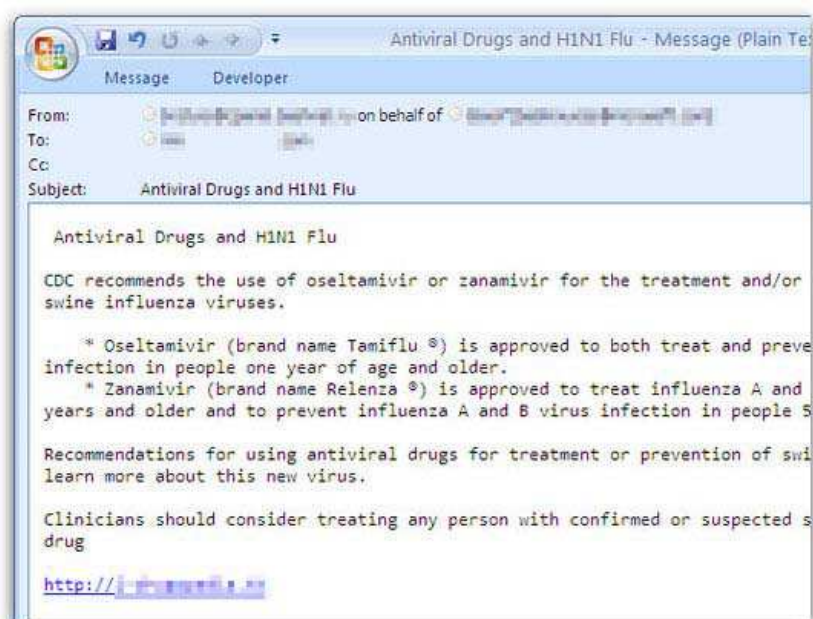
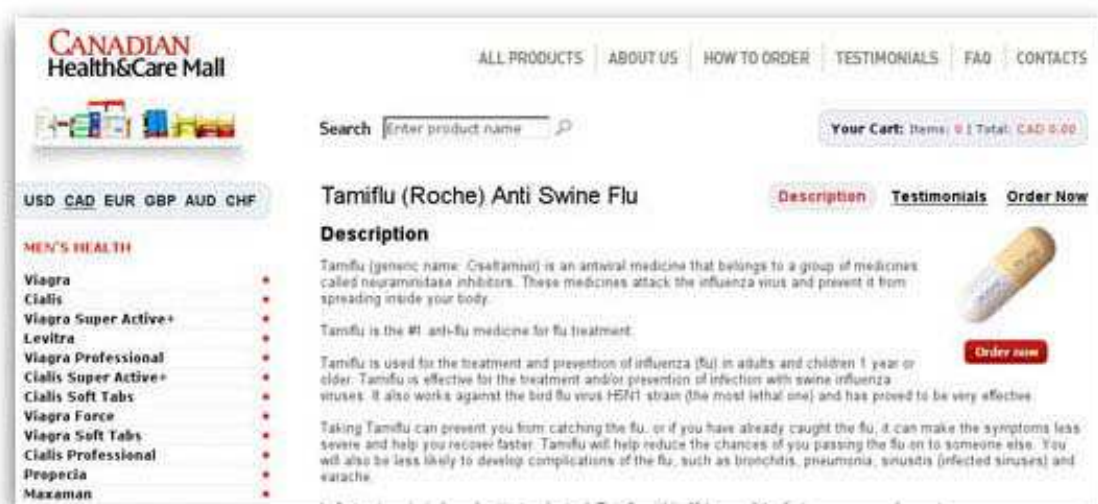


Figure 15: Messages from Russian cybercriminals said to have targeted UK citizens during the swine flu crisis. Source: Graham Cluley, "Swine flu fears making millionaires out of Russian hackers, Naked Security Blog", *Sophos*, November 16, 2009.

The case of Fukushima is also significant and following the nuclear accident in March 2011, two Japanese traffickers sold "Premium Zeolite" on line, stating that this counterfeit medicine would protect against radiation.²⁹⁴

According to the researcher Roger Bate it is important to use the Internet's potential as it can prove particularly useful for quick, safe purchases in a pandemic when buying medicines in a crowded pharmacy can present health risks. The solution would be to standardise the legal websites and start educating consumers and other stakeholders. A European medicine logo to mark legal Internet sales websites is planned for 2014²⁹⁵ and some

²⁹⁴ Sarah Imber, "Online Snake Oil Salesmen Exploit Japanese Radiation Fears", *SafeMedicines.org*, April 14, 2011. <http://www.safemedicines.org/2011/04/online-snake-oil-salesmen-exploit-japanese-radiation-fears-215.html> (access May 2, 2012).

²⁹⁵ ATS, "L'UE renforce sa législation contre les médicaments contrefaits", *Agence Télégraphique Suisse*, February 16, 2011.

experts believe that it will take up to ten years to set up a traceability system in Europe. The Internet network of the future²⁹⁶ must be seen as a 'global interconnecting network' that is extremely efficient in times of emergency or disaster. An 'emergency Internet' must therefore be used in addition to conventional communication means.

But beyond these emergency situations, there are also cybercrime cases in which the cybercriminals have a longer-term strategic vision. Glavmed is a significant example of this.

- Glavmed

The sale of medicines on the Internet generally works on the principle of an affiliation platform²⁹⁷ and these illicit networks can include from 3 or 4 affiliated sites up to several thousand. Glavmed, as we will see, is one of the most significant cases of cybercrime in the pharmaceutical sector, but there are between 100 and 200 other smaller networks, according to Legitscript.²⁹⁸

These illicit online networks have several methods in common²⁹⁹:

- The illegal online pharmacy networks claim to supply low-cost legal medicines.
- A lot of these networks sell mainly 'comfort' medicines but others offer a wider range of products.
- Some websites focus on branded medicines while others offer only generics.
- Some websites offer both branded and generic medicines but complaints from consumers indicate that even for purchases of branded medicines, a generic is always sent.
- Some networks never deliver the counterfeit medicines.

One important affair in the illicit trafficking of counterfeit medicines recently opposed two Russian businessmen involved in cybercrime: Pavel Vrubleisky and Igor Gusev³⁰⁰. Pavel Vrubleisky is the former CEO of Chronopay, a leading Internet payment system in Russia. He is currently in prison, charged with conducting illegal activities in online pharmacy affiliation programmes called RX-Promotion. Igor Gusev co-founded Chronopay with Vrubleisky in 2003, but following a conflict brought to light in 2005, Gusev left the company and founded his own illegal pharmacy affiliation programmes: GlavMed and SpamIt. These two affiliation programmes have dominated the fake online pharmacy market worldwide, but SpamIt was closed down in September 2010. Gusev has since been accused of practising illegal activities and is said to be on the run. In 2009, the two Russian businessmen brutally confronted each other publicly and commercially, each trying to bring down the other's programmes.

²⁹⁶ Dimitri Papadimitriou (ed.), *Future Internet, The Cross ETP Vision Document*, January 8, 2009.

²⁹⁷ By affiliation platform we mean a technological and counselling solution which puts the affiliators in contact with a network of pre-selected affiliates to promote their products. In return for managing the affiliation programme and providing the network of affiliates, the platform takes a commission on all the money transfers between the affliator and the affiliates.
Source: <http://www.e-marketing.fr/Definitions-Glossaire-Marketing/Plateforme-d-affiliation-6921.htm>

²⁹⁸ LegitScript, "Thinking Through Rogue Affiliate Pharmacy Networks", *LegitScript Blog*, November 26, 2010.
<http://legitscriptblog.com/2010/11/thinking-through-rogue-affiliate-pharmacy-networks> (access 2 May 2012).

²⁹⁹ Ibid.

³⁰⁰ Brian Krebs, "Pharma Wars", *KrebsOnSecurity*, February 25, 2011.
<http://krebsonsecurity.com/2011/02/pharma-wars/> (access 2 May 2012).

How Glavmed worked

Glavmed in fact had two affiliation programmes³⁰¹:

- one with purchases by consumers from sites promoted through affiliates of SpamIt,
- the other with orders from sites promoted by regular members of Glavmed using search engines and hacking techniques.

In general, SpamIt managed the 'suspect' activities (spamming campaigns, etc.) for sites selling medicines on line, including the huge Canadian Pharmacy network, while GlavMed provided 'honourable' showcasing for affiliation sites of online pharmacies (...). 'Honourable' in appearance only, as a study of the messages exchanged on Glavforum³⁰² led to the discovery of discussions between affiliates proving that they knew that their PharmacyChecker³⁰³ or other certificates were fake.



Figure 16: Glavmed - SpamIt affiliation model

Source: Brian Krebs, "SpamIt, Glavmed Pharmacy Networks Exposed", *KrebsOnSecurity*, February 24, 2011.

The affiliates of Glavmed / SpamIt had 'prefabricated' online pharmacies. They picked up about 40% of commissions on sales made on their website. Eight out of the ten largest affiliates of Spamit.com earned over USD 1 million in commission on their website. The motivation of these e-pharmacy affiliates was to generate cash as quickly as possible.³⁰⁴ The largest affiliates of SpamIt could hope to earn between USD 5,000 and USD 50,000 a month in commission.

³⁰¹ Ibid.

³⁰² Glavforum is the Glavmed online forum, www.glavforum.com.

³⁰³ PharmacyChecker is a company that until 2010 supplied certification services for online pharmacies aimed at the most popular search engine.

Source: <http://www.safemedicines.org/2009/12/checking-the-facts-on-pharmacycheckercom.html>

³⁰⁴ Donald E. deKieffer, "The Internet and the Globalization of Counterfeit Drugs", *Journal of Pharmacy Practice*, vol. 19, No. 3, 2006.

The websites promoted under the name 'Canadian Pharmacy' by affiliates of Glavmed / SpamIt were by far the most promoted by spam in June 2010.

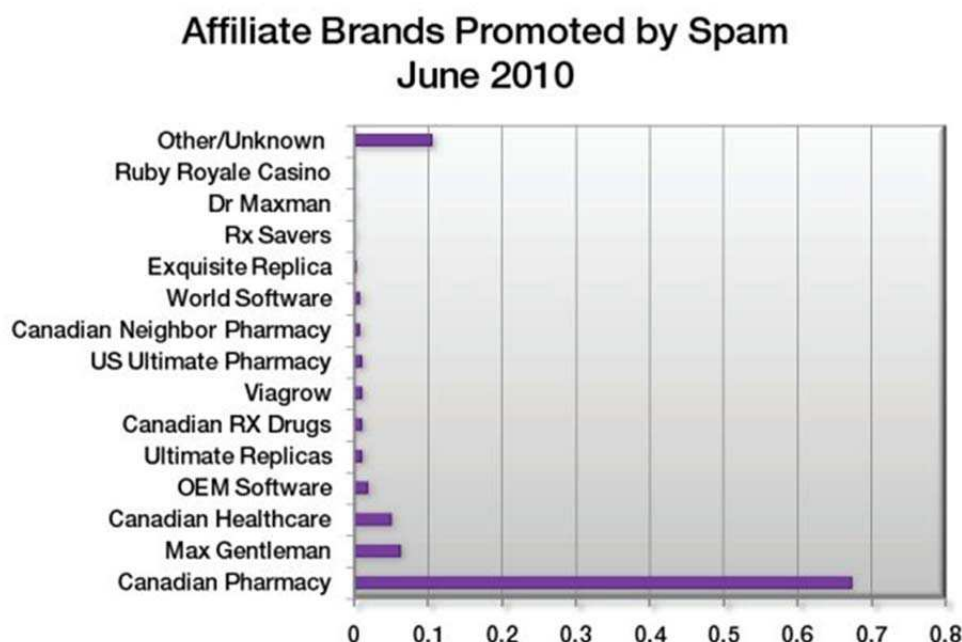


Figure 17: Affiliate brands promoted by spam.
Source: M86 Security Labs, June 2010.

SpamIt³⁰⁵ is said to have been the biggest distributor of counterfeit medicines on the Internet with over 1.5 million orders from 800,000 cyber buyers between May 2007 and June 2010. For three years, over 2,500 affiliates were able to earn significant commission by promoting the Glavmed pharmacy websites.³⁰⁶

According to sources obtained by hackers in 2010³⁰⁷, the second biggest member of the SpamIt network, called GeRa, is said to have enabled SpamIt to generate 80,000 sales of counterfeit medicines and USD 6 million in revenue over three years. GeRa was also linked to a large spambot that could send 18 billion emails a day.

Most of the SpamIt affiliates were paid in Webmoney, a virtual currency similar to PayPal. The payment system ePassporte was used for these payments. Following the closure of SpamIt by the Russian authorities in October 2010, the volume of spams fell drastically (around 40% at the beginning of October 2010³⁰⁸) particularly because the SpamIt affiliates were in a transition period during which they were looking for other partners. But GlavMed

³⁰⁵ Brian Krebs, "Pharma Wars", *KrebsOnSecurity*, February 25, 2011.
<http://krebsonsecurity.com/2011/02/pharma-wars/> (access on May 2, 2012).

³⁰⁶ Brian Krebs, "SpamIt, Glavmed Pharmacy Networks Exposed", *KrebsOnSecurity*, February 24, 2011.
<http://krebsonsecurity.com/2011/02/spamit-glavmed-pharmacy-networks-exposed/> (access on May 2, 2012).

³⁰⁷ Brian Krebs, "Who's Behind the World's Largest Spam Botnet?", *KrebsOnSecurity*, February 1, 2012.
<http://krebsonsecurity.com/2012/02/whos-behind-the-worlds-largest-spam-botnet/> (access May 2, 2012).

³⁰⁸ According to M86 Security Labs, "Spam Affiliate Program SpamIt.com to Close", *KrebsOnSecurity*, February 2011.
<http://krebsonsecurity.com/2010/09/spam-affiliate-program-spamit-com-to-close/>

remained active after the closure of SpamIt. In 2011 cybersecurity researchers valued the monthly income of GlavMed at over USD 1 million.³⁰⁹

GlavMed has no hesitation in advertising on the search engine Bing by pirating advertisements of legal Canadian sites (canadrugs.com, prescriptionpoint.com) to redirect them to an illegal Russian site canadian-healthcare-shop.com.³¹⁰

Note that WebMoney has gradually withdrawn from financing cybercriminal activities³¹¹ especially after signing contracts with conventional companies such as Steam, a US company specialising in online video games. And ePassporte was closed down in September 2010 due to fraud. It is important to remember that online payment method setups are very closely linked to the development of these online pharmacy affiliation networks. Chronopay was at the centre of the payment system for the RX-Promotion network.

- Russia

Links have also appeared between the cybercriminals in the GlavMed/SpamIt network and the Russian Business Network³¹². According to a confidential report³¹³ “The RBN offers a full infrastructure for illicit activities on the Internet in child pornography, games, phishing, spamming, virus spreading and more. Some experts use the term *cybercrime provider*. The RBN guarantees that the servers will not be closed down, even if a complaint is made; this is what we call *bulletproof* servers. (...) The RBN should be understood as a service designed and intended for criminals and mafia groups of all kinds which manages technology platforms to protect their illegal cyberactivity.”

Russia plays a major role in cybercrime linked to counterfeit medicines even if other regions probably also have a strategic role in this field (Eastern Europe, Brazil, China, etc.).

According to a recent study³¹⁴, Russia represents a total of USD 2.3 billion on the world cybercrime market, valued at USD 12.5 billion. The Russian-speaking world accounts for USD 4.5 billion, or more than a quarter of the world cybercrime market. The study also estimates spam emanating from Russia at a total of USD 830 million and the proportion of spam connected to the distribution of counterfeit medicines at 6.2% of the total Russian cybercrime market, or USD 142 million. A particularly worrying fact is that Russian cybercriminals apparently have increasingly organised, large-scale structures which are close to the organisations linked to the more traditional sectors of organised crime (prostitution, drugs, arms dealing, etc.).

In terms of activity, figure 18 below³¹⁵ shows the links between ‘economic profit’ and ‘number of incidents’. Spams and online banking fraud are shown to be the most profitable activities. Cybercrime concerning counterfeit medicines are somewhere in the middle.

³⁰⁹ Chris Kanich, Tristan Halvorson, et al., “Show me the Money, Characterizing Spam-advertised Revenue”, *USENIX Security Symposium*, 2011, San Francisco, USA.

³¹⁰ Knujon and Legitscript, No Prescription Required: Bing.com Prescription Drug ads, August 4, 2009.

³¹¹ CEIS, Study directed by Guillaume Tissier, *Les marchés noirs de la cybercriminalité*, June 2011, p. 44.

³¹² The RBN is a nebulous Russian network with cybercriminal activities on the Internet. For further information, read David Bizeul, *Russian Business Network Study*, November 20, 2007.

³¹³ Source: IRACM.

³¹⁴ Robert Lipovsky, Aleksandr Matrosov and Dmitry Volkov, “Cybercrime in Russia: Trends and issues”, *Group IB*, 2011. Source: <http://securityaffairs.co/wordpress/4686/cyber-crime/russian-cybercrime-not-only-a-localized-threat.html>

³¹⁵ Ibid.

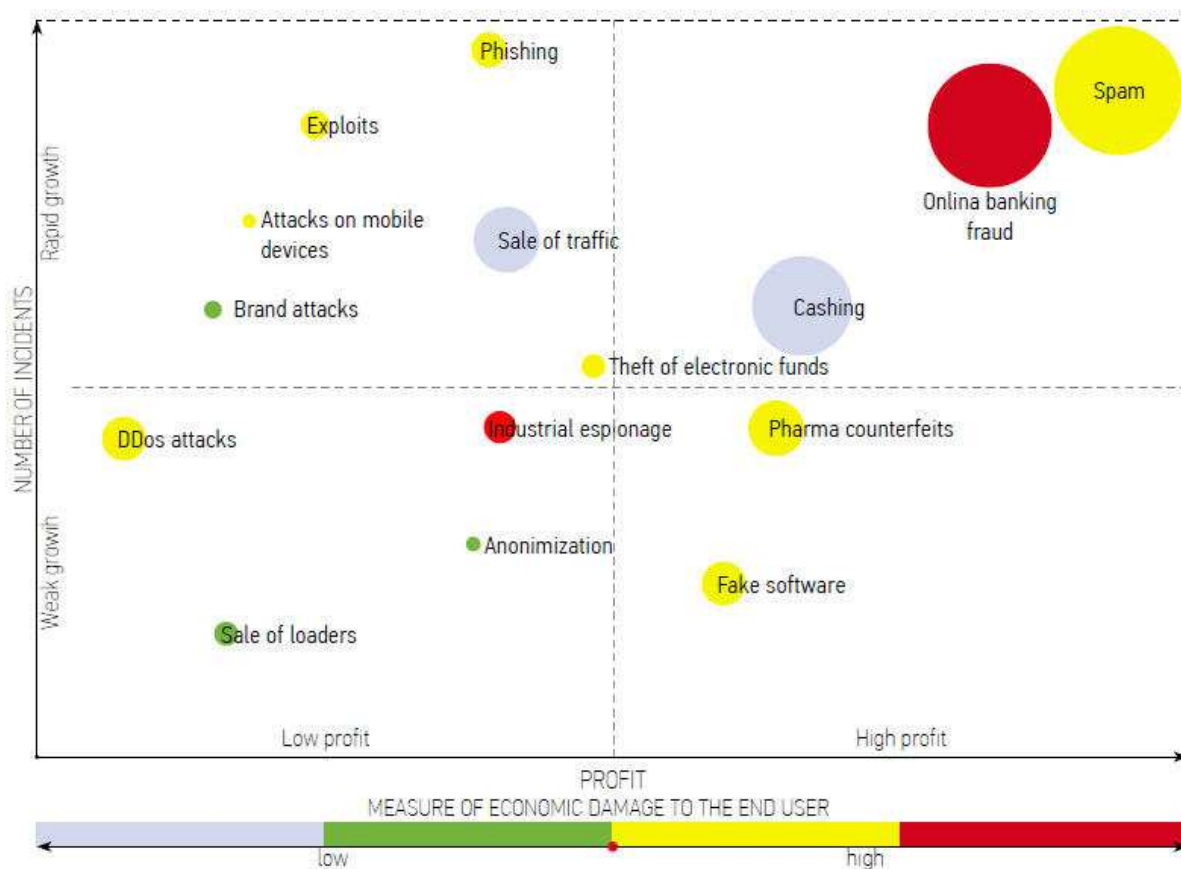


Figure 18: Relation between profit and number of incidents.

Source: <http://securityaffairs.co/wordpress/4686/cyber-crime/russian-cybercrime-not-only-a-localized-threat.html>

II.7. A summary of the criminal organisations involved in counterfeiting medicines: organisational challenges

At the end of our study, how can we distinguish the criminal organisations involved in counterfeiting medicines in the 'real' and 'virtual' worlds?

II.7.a. 'Real' criminal networks and medicine counterfeiting

It is important to underline the importance of the network concept and observe the transnational criminal networks very closely in our study.

- The importance of the network concept

The network concept is particularly suited to today's economy: "The specialisation era has become the network as such and its ability to supply, transport and deliver illicit goods to various countries. The actual type of goods in question is now of secondary importance."³¹⁶

Generally speaking, the 'criminal network' concept seems more appropriate than 'criminal organisation'. The network-style organisation dominates, with for example "central figures who initiate the projects, settle conflicts and give guidelines to all the players. In this structure, activity moves from the centre towards the players on the outer edges, and these have no contact with each other".³¹⁷ This organisation is particularly common in China³¹⁸ where a unit (often a trading unit) dominates a spider web structure (called *zhizhuwang* in Chinese) with authorised interactions between the outer units. This organisation does not exclude a leader or group leader but it is predominantly the "network of networks" pattern at the top of a pyramid structure. One variant is a network structure with no interaction between the outer units but with an entrepreneur-coordinator in the centre who isolates all the contacts. This pattern is often found in drug trafficking in China³¹⁹. Another advantage of the network is that it weakens the legal instruments that are often held up by bureaucracy or slow decision-making processes. But conversely, over-compartmentalising structures can hamper the steady flow of information and can also lead to excessive risk-taking by the units on the edge who can then challenge the central leaders and create instability within the organisations.³²⁰

Often in counterfeiting, "the criminal networks become traders, middlemen between supply and demand, facilitators of illegal international trade".³²¹ This 'trader' approach has been confirmed in the pharmaceutical sector by Nie An³²², CEO of the company Honor International Pharmtech, which was investigated by customs officials. According to Nie An, "We do not really have factories. Honor International is just a trading company. (...) As a trading company, stating that you can take charge of production attracts business. It is false advertising."

This statement could also have applied to Kevin Xu who was more of a middleman than a manufacturer.

Generally speaking, one feature of these networks is that they adapt easily to market conditions. The Chinese 'traders' involved in counterfeiting are able to segment the market according to buyers' demands and prices of counterfeit medicines can vary according to the quantity and quality of the active pharmaceutical ingredients contained in the products. This technique enables traders to sell off their counterfeits cheaply and in large quantities without lowering their profit margins or conversely to sell more sophisticated medicines in more closely regulated markets.³²³ Our numerous examples have shown us that criminal organisations use networks in a more pragmatic way than the law enforcers³²⁴, which gives these organisations a definite advantage in terms of

³¹⁶ Fausto Zuccarelli, *The phenomenon of trademark counterfeiting and organized crime. Domestic and international investigations for contrasting illegal replication activities*, 2006, p. 7.

³¹⁷ Jerome P. Bjelopera, Kristin M. Finklea, "Organized Crime: An Evolving Challenge for U.S. Law Enforcement", Congressional Research Service Report for Congress, December 23, 2010.

³¹⁸ Ming Xia, "Organizational Formations of Organized Crime in China: perspectives from the state, markets, and networks", *Journal of Contemporary China*, vol. 17, No. 54, 2008.

³¹⁹ *Ibid.*

³²⁰ Mette Eilstrup-Sangiovanni, Calvert Jones, "Assessing the Dangers of Illicit Networks: Why al-Qaida May Be Less Dangerous Than Many Think", *International Security*, vol. 33, No. 2, autumn 2008, p. 7-44.

³²¹ Mickaël R. Roudaut, *Marchés criminels. Un acteur global*, Presses Universitaires de France, 2010, p. 32.

³²² Walt Bogdanich, "Chinese chemicals flow unchecked onto world drug market", *The New York Times*, October 31, 2007.

³²³ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 185.

³²⁴ Mette Eilstrup-Sangiovanni, "Transnational networks and New Security Threats", *Cambridge Review of International Affairs*, vol. 18, No. 1, April 2005, p. 7-13.

speed and efficacy. "It is very difficult to track counterfeiters' production sites and their distribution networks and therefore to arrest them."³²⁵

As we have seen, two types of criminal organisations seem to dominate in the most significant cases of counterfeit medicines:

- Either actors with some sort of connection with the pharmaceutical sector (see the Peter Gillespie and Kevin Xu cases, pages 44 and 59). These horizontal organisations are often of medium size (from three or four people to ten or so in the centre of the network).
- Or criminal organisations that are closer to a "conglomerate" with "very large operators which have taken over a small-scale diaspora activity which controlled the trafficking throughout the 20th century."³²⁶ In this case the organisations can be highly complex with industrial facilities and others more geared towards marketing and finance. This kind of network tends to be polymorphic with a structure that regenerates or adapts to opportunities and can therefore direct its actions towards a variety of fields (particularly by targeting Europe and the US). It seems difficult to anticipate or even to follow such a complex network closely enough without being able to infiltrate the heart of the strategic decision-making core as we saw in the case of the huge Middle East network.

There is also the question of the transnational dimension of these networks.

- Transnational criminal networks

As we have seen, the case of mafia groups (or triads, cartels, etc.) would benefit from greater clarification as there is very little "analysis of the flows of international economic exchange"³²⁷ connected with these criminal structures which have diversification strategies that might involve them in counterfeiting medicines which in turn, as we have observed, has certain links with the narcotics market. Yet there has been little study of this diversification strategy at global level, particularly when it combines legal and illegal activities.³²⁸ Examination by specialists of this type of organisation (researchers, magistrates) would confirm whether or not this type of structure exists and would keep a watchful eye over any future involvement.

It would be an analytical error to attribute to these transnational criminal networks (and particularly mafia groups or their equivalents) "a transnational scapegoat function, symbolising the dangers and damage related to economic and institutional globalisation and privatisation processes".³²⁹ These illegal networks often take advantage of local corruption, but also work closely with legal structures (free zones, transport companies, etc.) that should also be associated as much as possible with these shifts resulting from the globalisation of trade. We have also observed that legal actors (importers or manufacturers) could sometimes become illegal actors and that criminologists should concentrate more on this 'transnational white-collar crime' in their studies.

Generally speaking the most internationalised criminal structures have acquired the ability to analyse the opportunities of certain markets, especially by testing certain strategies likely to expand their field of action³³⁰. "There are no ordinary, constant networks but rather a multitude of transit countries, most often selected for their lack of thorough verifications. But some places are hubs."³³¹ That said, it is also truly difficult to analyse these

³²⁵ Albert I. Wertheimer, Perry G. Wang, *Counterfeit Medicines Volume I: Policy, Economics and Countermeasures*, ILM Publications, 2012, p. 15.

³²⁶ Michel Koutouzis, Pascale Perez, *Crime, trafics et réseaux. Géopolitique de l'économie parallèle*, Ellipses, 2012, p. 25.

³²⁷ Cesare Mattina, "The transformations of the contemporary mafia: a perspective review of the literature on mafia phenomena in the context of the internationalisation of the capitalist economy", *International Social Science Study*, vol. 62, No. 203-204, March-June 2011, p. 229-245.

³²⁸ Ibid.

³²⁹ Maria-Luisa Cesoni, *Criminalité organisée: des représentations sociales aux définitions juridiques*, LGDJ, 2004, p. 734.

³³⁰ Klaus von Lampe, "Re-conceptualizing Transnational Organized crime: offenders as problem solvers", *International Journal of Security and Terrorism*, vol. 2, No. 1, 2011, p. 1-23.

³³¹ Union des Fabricants, *Contrefaçon & criminalité organisée*, 3rd edition, 2005.

networks and anticipate their form and nature, as in some cases, “there is no way of knowing in advance how the groups or statutes are made up, or how the various relationships are combined”.³³² A frequent feature of these networks is their “hybridisation”³³³ especially in counterfeit medicines where we have seen the variety of groups involved: Chinese manufacturers, smugglers, pharmaceutical sector wholesalers, corrupt customs officials, Chinese or Russian soldiers, Russian cybercriminals, white-collar crime, presumed mafia involvement, etc. The difficulty lies in finding out where and when sub-networks can incorporate into each other or even mutate in different directions. With these constant changes “the media and government radars have an inherent difficulty in detecting the clandestine and changing criminal phenomena far enough in advance”³³⁴ and the investigation services in the pharmaceutical sector seemed more involved in real current issues. “One thing is sure, these operations are wide reaching”³³⁵ and international orders can come from a variety of regions often involving Chinese operators with hubs in India, East Africa, the Middle East and Southern Europe.

Finally, however important the transnational commercial exchange has become and however complex it is to guarantee accurate traceability, in the most opaque criminality, particularly industrial, often “it is at *local* level that organised crime shows itself as a tangible activity”.³³⁶ The challenge for the law enforcers is to gain access to these sources domiciled in areas difficult to access. The case of major new industrialised countries like China addresses the issue of this local dimension with acuity. And the Internet, that “network of networks” poses specific challenges in criminality for our field of study.

II.7.b. ‘Virtual’ criminal networks and counterfeit medicines

We will begin by describing the organisational features of these ‘virtual’ criminal networks, and then we will examine their connections with the ‘real’ criminal networks.

- Organisation

For criminals “the most significant transformation from the streets to cyberspace is the enlarged playing field of individuals and organised groups. Enabled by the Internet, criminals can operate in cyberspace with less governance, and on a transnational scale”.³³⁷ In general, the “cybercriminal” organisations differ from traditional criminal organisations by their greater fluidity. Cybercrimes are committed by multitasking and virtual criminal networks also hold online meetings.³³⁸ These networks are based on independent individual units as the members rarely meet in real life and sometimes do not even have any virtual contact with other colleagues. The virtual criminal networks are often managed by a small number of criminals who do not actually commit any crimes themselves but act more as ‘entrepreneurs’ as we saw with Igor Gusev, founder of the Glavmed network (p. 94).³³⁹ Cybercriminal actions (spamming, data processing, etc.) are compartmentalised into different segments of responsibility.

It is important to specify that since the mid-2000s the Internet has led to the fragmentation of crime and trafficking of counterfeit products supplied by thousands of ‘transporter ants’. Internet has perhaps led to an even

³³² Alain Degenne, Michel Forsé, *Les réseaux sociaux*, Armand Colin, 1994, p. 7-16.

³³³ François Farcy, Jean-François Gayraud, *Le renseignement criminel*, CNRS éditions, 2011, p.17.

³³⁴ François Farcy, Jean-François Gayraud, *Le renseignement criminel*, CNRS éditions, 2011, p.18.

³³⁵ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 187.

³³⁶ Dick Hobbs, “Going Down the Glocal: The Local Context of Organized Crime”, *The Howard Journal*, vol. 37, No. 4, 1998, p. 407-422.

³³⁷ Joan E. Foltz, “Global Crime Case: Cybercrime and Counterfeiting”, *Futurist*, November 1, 2008.

³³⁸ Tatiana Tropina, “Cyber Crime and Organized Crime”, *Freedom For Fear Magazine*, No. 7, July 2010.

³³⁹ Ibid.

more individualised form of criminal organisation.³⁴⁰ Information technology tools are now widely available, to such an extent that any Internet user could turn into a potential “cybercriminal”. This development has been aided by the fact that cybercriminals’ identity is not only anonymous but also universal and that their phishing techniques are common and relatively easy to implement on the Internet (the so-called bulletproof³⁴¹ servers preserve anonymity). Another feature that has helped this development is the automation of so many processes which makes it more difficult to adhere to a rigid hierarchical organisation on the Internet compared to the real world where individual effort is the best strategy in criminal organisations.³⁴² On the Internet the concept of power or violence has nothing to do with an accumulation of the “physical strength” of the various computer hackers or pirates.³⁴³ The more strategic skills now lie in automated processes. Automation is becoming increasingly accessible to Internet users, particularly if they want to become involved in counterfeit medicine networks.

That said, this individualisation should be qualified, as from a global viewpoint a particularly effective cybercrime setup cannot function if the organisation is too small. As we saw with the Glavmed case and illicit online pharmacies, using huge networks of affiliates combines an individualised and compartmentalised organisation with a complex overall structure. Cybercrime structures such as these also have high level experts who can be easily solicited by the central actors in these organisations to optimise their “criminal network”³⁴⁴ with for example financial advice (money laundering) and technical advice (hosting on servers protected from law enforcers).

When examining criminal organisations on the Internet involved in counterfeit medicines, our previous studies have brought to light two types of structure.

The first are opportunistic online networks which can be set up *ad hoc*, coinciding with ‘real’ flows, during distribution to the end consumer. The RxNorth and Wuppertal affairs come under this category where members act on the Internet for a limited time and on specific tasks.³⁴⁵

A second category of organisation is exclusively devoted to online distribution and promotion with globalised affiliation techniques and aggressive promotion on search engines or via spam. The Glavmed case is a revealing example of such organisations, generally domiciled in emerging countries. Paradoxically, these Internet networks seem better organised and more coherent than the organisations involved in counterfeiting medicines in the real world. The affiliation and promotion techniques for counterfeit medicines correspond to relatively clear management strategies and a careful watch can help us to understand the networked organisation set up.

- Relations between ‘virtual’ criminal network and ‘real’ criminal network

If cybercrime was initially distinct from more conventional criminal organisations, it appears that the two networks are somewhat similar, particularly in the case of medicines where cybercriminals have to find supplies from illicit production sources. It is worth noting however that it is not easy to analyse and therefore confirm any actual links between real criminal networks and others that are more ‘virtual’. Although the online pharmacies necessarily obtain supplies from industrial structures, the nature of these links remains vague and many

³⁴⁰ Klaus von Lampe, “The Interdisciplinary Dimensions of the Study of Organized Crime”, *Trends in Organized Crime*, vol. 9, No. 3, 2006, p. 77-95.

³⁴¹ Bulletproof servers are those which host illicit activities such as spreading spam.

³⁴² Susan W. Brenner, “Organized Cybercrime? How Cyberspace May affect the Structure of Criminal Relationships” in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 97.

³⁴³ *Ibid*, p. 75.

³⁴⁴ Jerome P. Bjelopera, Kristin M. Finklea, “Organized Crime: An Evolving Challenge for U.S. Law Enforcement”, *Congressional Research Service Report for Congress*, December 23, 2010, p. 29.

³⁴⁵ The researcher Kim-Kwan Raymond Choo has theorised this temporary online mobilisation of criminal organisations. Kim-Kwan Raymond Choo, “Organised crime groups in cyberspace: a typology”, *Trends in Organized Crime*, vol. 11, No. 3, 2008, p. 270-295.

observers seem to ignore them. But in general, the two networks are more or less distinct and it seems that in most of the cases observed and indexed, and contrary to what some researchers like Julie Lynn Olson think,³⁴⁶ to our knowledge, there is no real fusion between the two types of network, particularly in medicines where the optimal distribution methods on the Internet and logistics in the real world have not created transnational organisations that can manage both types of illegal trafficking for any length of time.

Criminal approaches differ in the two environments and we can currently distinguish between three different examples:

- Criminal organisations involved in the 'real' world but without any real impact on the 'virtual' (for example, the Kevin Xu affair).
- Criminal organisations originally involved in the 'real' world but which use Internet to distribute their counterfeit products (for example the RxNorth affair).
- Criminal organisations which focus their skills on the 'virtual' world (for example Glavmed).

It can be supposed that a structure combining large-scale trafficking of counterfeit medicines on line and in the physical world would have little chance of surviving for any length of time as an organisation like that would be more visible where the 'real' connects with the 'virtual' and paradoxically would gain less benefit from the systemic flaws because of a defect in the organisation. That said, it is true that both types of organisation tend to be modelled on similar organisations and, as Olson³⁴⁷ notes, "the characteristics traditionally attributed to conventional organisations can also be attributed to cybercriminals". One wonders if it is not the traditional organisations that take their inspiration voluntarily or *de facto* from the specific qualities of cybercriminal organisations: best possible use of the network, fairly horizontal structure with only a very small nucleus of decision makers, sense of ubiquity, fast execution, flexibility, a knack of finding loopholes, etc. A hacker's manifesto³⁴⁸ is very revealing of how the "TAZ: Temporary Autonomy Zones" work; for the cleverest traffickers, these can overlap into the 'real' world: "(...) appearing - disappearing to better escape from the government surveyors, it temporarily occupies an area (of land, of time, of imagination) and then breaks up as soon as it is named. The TAZ avoids the named TAZs, the areas "conceded" to freedom: it takes by storm, and goes back to being invisible. (...) A TAZ can only exist if it maintains a certain level of anonymity."

But in the case of cybercrime organisations, such Temporary Autonomy Zone characteristics can be pushed to the extreme because challenging the concept of borders and the general immediateness of actions are specific to the 'virtual' world. Another trend³⁴⁹ specific to cyberspace: "the proliferation of counterfeiting on the Internet can also be explained by an interconnection between minor trafficking and serious crime. A small-time home-based dealer can contact mafia networks for example. Breaking up the chain dilutes criminal liability". This analysis is particularly relevant in the case of illegal online pharmacies which operate by mixing a highly criminal core network with partners who are Internet users seeking illegal surplus income.

To sum up, it is especially important not to consider such 'real' or 'virtual' organisations as tentacle-like structures with fixed strategies. "The widest and most incorrect theory is that there is a unified conspiracy in counterfeiting and criminal organisations. (...) It is more likely that the counterfeiting economy operates in parallel with the legal economy with a kind of assembly of different submarkets".³⁵⁰ Although most cases are white-collar

³⁴⁶ Julie Lynn Olson, *The threat of systematic and organized cybercrime and information warfare*, American University, School of International Service, 2004.

³⁴⁷ Ibid.

³⁴⁸ Hakim Bey, *TAZ: Zone d'autonomie temporaire*, Editions de l'Eclat, 1998.

³⁴⁹ Source: David Hervé Boutin, Cabinet Director for the President of the National Anti-Counterfeiting Committee (CNAC), interviewed by Caroline Heurtault in "Dossier. Des gendarmes infiltrent les forums d'adolescents. La contrefaçon, l'autre versant de la cybercriminalité", *La Croix*, August 27, 2009.

³⁵⁰ This viewpoint of David S. Wall in fact concerned the fashion industry but can also be applied to the pharmaceutical industry. Jo Large, David S. Wall, "Jailhouse Frocks, Locating the Public Interest in Policing Counterfeit Luxury Fashion Goods", *British Journal of Criminology*, vol. 50, No. 6, July 2010.

crime-related, we have also seen a great variety of situations, particularly with organised crime-type structures able to seize criminal opportunities in pharmaceuticals (Wuppertal case) but also hybrid transnational networks that are particularly tough to track and dismantle.

Generally speaking, “the last globalization wave was both an opportunity and a challenge for these traditional criminal organisations. This has led a number of authorities to argue the fact that they are gradually being “replaced by smaller, more flexible groups”, or even by “networks”. (...) Without an autonomous institutional identity, they are no more than business connections between individuals of varying durations”.³⁵¹ A point of view particularly suited to the different patterns observed in medicine counterfeiting dominated by flexible autonomous groups and even large businesses, such as the ‘Jordanian-Chinese’ network should be understood according to a system of fluctuating opportunistic networks and subnetworks. It is also important not to presume that, in these most significant ‘real’ or ‘virtual’ criminal networks, each operator is in contact with all other operators in the network but instead that each member operates within nodes, connections and intermediate structures. Only the most strategic members liaise while the other members tend to operate relatively independently or in isolation.³⁵² As for the particular case of traditional criminal structures that can be characterised by the use of violence, more or less secret initiation rites and a long history, their involvement seems likely in certain regions (triads in China, cartels in Latin America, for example) but there is only scattered evidence, which is insufficient to accurately confirm such involvement. Whatever the case, it would appear that such organisations operate more on the edge of counterfeit medicine trafficking, particular when transnational. That said, the question, one that is outstanding with our open source information, arises of possible cooperation between white-collar crime organisations and more traditional ones involved in trafficking habitually linked to organised crime. For some researchers ‘partnerships’ (rather than mere ‘transactions’) between these two networks are obvious³⁵³, but as we have seen, they have yet to be specified and confirmed in the case of medicine counterfeiting.

³⁵¹ UNODC, The globalization of Crime, A Transnational Organized Crime Threat Assessment, 2010, p. 28.

³⁵² Vincenzo Ruggiero, “Fuzzy criminal actors: Introduction”, Crime, Law & Social Change, vol. 37, No. 3, 2002, p. 177-190.

³⁵³ Ibidem.



III. Criminological issues and recommendations

The purpose of this third part is to show to what extent counterfeit medicines shake up traditional criminological concepts. We will then suggest ideas to counter this phenomenon.

III.1. Shaking up criminological concepts

Our discussion will be in two parts: first we will show that criminological concepts remain partially valid for deciphering criminal issues surrounding counterfeit medicines. Then we will highlight certain new academic aspects.

III.1.a. A partially suited theoretical view

In light of the ‘networks’ involved in medicine counterfeiting are criminological theories appropriate?

To a certain extent we can answer in the affirmative. Indeed, the concept of mimicry according to Gabriel Tarde³⁵⁴, a criminology reference of the 19th century, appears to be valid in the case of ‘counterfeiting criminals’, which is inherently based on counterfeiters’ desire to imitate original medicines as best they can, as far as their appearance is concerned anyhow. Certain drug copies can therefore appear to be flawless.³⁵⁵ Also, to infiltrate certain markets, counterfeiters must ‘mimic’ the system in place based on the pharmaceutical industry’s models. The only difference is that the production, packaging, distribution, marketing and financial structures launder the income from these illegal sales.³⁵⁶ We can also assume that the fragmentation of the pharmaceutical supply chain inspires these networks’ counterfeit medicine flow management techniques, helping them to evade law enforcement authorities. In such a context, the criminological concept of “situational prevention”³⁵⁷ appears to be strategic and still topical. Indeed, mastering the manufacture of medicines and protecting transport flows or flows on the Internet involves prevention techniques that are essential for operators who may be targeted by counterfeiters.

White-collar crime is also an important area of discussion.

According to the American Edwin H. Sutherland³⁵⁸ who founded this concept, white-collar crime is characterised by the fact that it attempts to “exploit a legitimate business by non-violent means, whereas organised crime (...) uses physical intimidation and violence to enforce discipline, secure its markets and punish informants”.³⁵⁹ Sutherland’s analyses remain partly relevant to our field of study. Indeed, his “theory of differential association

³⁵⁴ Gabriel Tarde, *La criminalité comparée*, Empêcheurs de Penser en Rond, 2004, p. 92.

³⁵⁵ Amir Attaran, Roger Bate and Megan Kendall, “Why and How to Make an International Crime of Medicine Counterfeiting”, *Journal of International Criminal Justice*, vol. 9, No. 4, May 2011.

³⁵⁶ Ibidem.

³⁵⁷ Maurice Cusson, *La criminologie*, Hachette, 2011, p. 65.

³⁵⁸ Edwin H. Sutherland, *White Collar Crime*, New York: Holt, Rinehart & Winston, 1949.

³⁵⁹ Tom Kubic, “IP Theft and International Organized Crime and Terrorism – The Emerging Threat”, *IPR Center, Symposium*, June 3, 2010.

argues that criminal behaviour is learned through the channel of interpersonal interactions by acquiring techniques to achieve crimes, attitudes, rationalizations and motives".³⁶⁰ All of which are stimulating elements in deciphering criminal networks where, as we have seen for the most sophisticated networks, it can be assumed that there are many interpersonal interactions between groups of diverse backgrounds involved in medicine counterfeiting activities.

Sutherland also stresses the concept of "anomie and normative conflicts" that can be expected to create an environment conducive to criminal behaviour. In such a context, criminals can be perceived "as the only guarantor and interpreter of the legal system"³⁶¹, particularly in cases where there is no "immediate perception of physical injury"³⁶², which can be applied to medicine counterfeiting, where the diluted chain of liability and impact of the drug's counterfeiting are rarely established accurately. This failure to accurately assess the health impact of counterfeit medicines fosters a form of self-justification among these white-collar criminals: "Illegal? Yes, but not criminal. I presume that a criminal action involves harm to a person, and we've never done that".³⁶³ Paradoxically this idea of white-collar crime being less dangerous than crime that is perceived as "more organised, violent and traditional" remains very present in public opinion³⁶⁴ and it is up to law enforcement authorities to clarify and stress further the predatory nature of such criminal behaviour dominant in medicine counterfeiting. It is also important to continue to obliterate the often mythological multiple roles attributed to criminals.³⁶⁵

This is all the more necessary as the profile of some leaders in medicine counterfeiting (Andrew Strempler) corresponds roughly to these conceptions of white-collar crime where "the crime is committed by a respectable person of high social status in the course of his occupation"³⁶⁶. While it is necessary to qualify this "high social status", for many business owners involved in counterfeiting activities (Peter Gillespie, Kevin Xu) the size of their company and the quantities of counterfeit drugs imported or manufactured meant that they had obvious responsibilities. We can also deem this 'aura' all the more unacceptable in counterfeit medicines as there is a real health impact resulting in death in some cases. However, we should avoid oversimplifying classifications as the profiles of criminals can vary due to the large number of 'criminogenic interstices' created by globalisation.

Can Sutherland's concept of "a white-collar crime of high social status" be applied in emerging countries, especially China? Are there not a variety of criminal situations that should be uncovered, with networks involved in medicine counterfeiting in various ways (hospitals, small manufacturers, drugstores, etc.)? How much are traditional criminal organisations (Chinese triads, South American cartels or even the Italian mafia) involved in this trafficking?

Our area of study in fact raises many questions.

³⁶⁰ Maurice Cusson, *La criminologie*, Hachette, 2011, p. 55.

³⁶¹ Amedeo Cottino, *White-Collar Crime*, in Colin Sumner, *The Blackwell Companion to Criminology*, Blackwell Publishing, 2003, p. 346.

³⁶² Ibidem.

³⁶³ James William Coleman, *The Criminal Elite. The Sociology of White Collar Crime*, New York: St Martin's Press, 1989, p. 213.

³⁶⁴ Amedeo Cottino, *White-Collar Crime*, in Colin Sumner, *The Blackwell Companion to Criminology*, Blackwell Publishing, 2003, p. 352.

³⁶⁵ Hans Magnus Enzensberger, *Politique et crime*, Gallimard, 1967, p. 25.

Between literature (Thomas de Quincey), humanities (Jacques Derrida) and cinema (de Palma, Coppola), there are abundant romantic perceptions of criminals. A vision undermined by the profiles of medicine counterfeiters.

³⁶⁶ Edwin H. Sutherland, *White Collar Crime*, New York: Holt, Rinehart & Winston, 1949.

III.1.b. The novel nature of criminological concepts linked to medicine counterfeiting

Between formalisation issues, cross-disciplinarity challenges and mapping problems, our criminological scope is clearly novel.

- Specific crime insufficiently formalised

As we have seen, white-collar crime dominates many significant 'criminal networks' involved in medicine counterfeiting.

Having said that, the organisational dimension of these networks is still not analysed sufficiently. According to Sutherland³⁶⁷, it is essential to better understand the 'organisational' dimension of this kind of crime, which can be 'formalised', particularly as "network structures" as previously discussed.

In this type of analysis there is the question of 'boundaries' and it is also important to bear in mind that there may be many factors binding governments with the economic environment³⁶⁸, and thus white-collar crime. The 'white-collar criminals' in question may therefore be shielded by personal or cultural ties. According to Sutherland it is essential to draw the strongest possible boundary between the government and the private sector for crime prevention to be consistent and effective.³⁶⁹

It would therefore be appropriate to formally classify white-collar crimes involved in medicine counterfeiting according to geographical area and the most significant cases. We have noticed that, paradoxically, white-collar crime is more visible than more traditional violent criminal organisations that may be involved in medicine counterfeiting. More precise research focusing on crime directly or indirectly linked to the pharmaceutical industry should therefore be encouraged, in particular to better assess risk areas and operators. It would also be appropriate to facilitate studies of how traditional criminal organisations become involved in medicine counterfeiting. Some regions (China and Latin America, for example) seem more appropriate for such research. But in general, we cannot help noticing that despite abundant literature on the subject, studies of traditional criminal organisations are too scarce, vary in quality, to say the least, or are too ideological. This situation is also applicable in the United States, where, in the early 80s, researcher Peter Reuter observed the scarcity of research studies.³⁷⁰

In criminological terms, our area of study challenges certain traditional views that generally emphasise a connection between marginality and criminal risk.³⁷¹ But contemporary crime and particularly cybercrime, if considered one of the most innovative forms of crime, puts such a relationship into perspective because today potentially anyone on the Internet can have access to criminal activity. New technologies (Internet, but also satellites, mobile communications, so-called virtual worlds, etc.) require the "rigid boundaries of police criminology" to be reconsidered, to focus on "criminogenic interstices"³⁷² to better understand modern-day

³⁶⁷ Edwin H. Sutherland, *White Collar Crime, The Uncut Version*, New Haven and London: Yale University Press, 1983, p. 229.

³⁶⁸ *Ibidem.*, p. 252.

³⁶⁹ *Ibidem.*, p. 257.

³⁷⁰ Peter Reuter, *Disorganized Crime: The Economics of the Visible Hand*, The MIT Press, 1983, p. 5.

³⁷¹ Majid Yar, *Cybercrime and society*, Sage Publications, 2006, p. 19.

³⁷² Source: the article by Carlo Morselli, Mathilde Turcotte and Guillaume Louis, "Le crime organisé et les contre-mesures" in Maurice Cusson, Benoît Dupont and Frédéric Lemieux (dir.), *Traité de sécurité intérieure*, Presses polytechniques et universitaires romandes, 2008, p. 186.

crimes³⁷³ and the organisational forms involved. “Criminogenic interstices” refer to the gaps left by public institutions both in services and regulations, which criminal organisations exploit”.³⁷⁴ ‘Real’ and ‘virtual’ ‘interstices’ or ‘loopholes’ that we previously analysed with various examples revealing the presence of criminal networks. In the ‘real’ world we noticed how much the emergence of new Chinese and Indian manufacturers, the size of free trade zones, the growth of trade and the complexity of the supply chain disrupt the traditional patterns of ‘criminal organisations’ connected to organised crime or organisations that generally have a strong structure and hierarchy. As for policing and investigation methods in the broadest sense (customs included), they come up against hurdles given the complexity and volatility of international trade not to mention the legal obstacles in certain investigations.

In light of such challenges in the representation of what is ‘real’ and ‘virtual’, there is an acute mapping issue.

- The mapping issue

Crime mapping, particularly inspired by statistics that allow the use of more or less scientific techniques, seem to have a limited application in the case of counterfeit medicines. Indeed, urban mapping techniques applied to crime present much more complex challenges on a global scale, primarily due to the difficulty of compiling statistics on certain areas where access to illegal trafficking data is difficult. That said, it is essential to map counterfeit medicine trafficking networks more effectively by an experimental approach and not to limit the mapping to mere seizure statistics.

For example, it would be encouraging to compile a list of areas most at risk with a specific set of parameters (tax benefits, local protection, corruption, unreachable digital servers, etc.). Such a list of vulnerabilities related to these targeted areas, compiled regularly in a visual form, would clarify the ongoing challenges and help to guide law enforcement tools and lobbying.

The mapped risks may for example distinguish regionalised risks, wide-reaching risks and network-related risks (real and/or virtual).³⁷⁵ Another strategic risk, one that is too often overlooked, concerns meeting points³⁷⁶. It is indeed difficult to know in which areas relations between ‘real’ counterfeit medicine trafficking and ‘virtual’ distribution is formed. Transition areas between the sale of counterfeit medicines and their ‘financial laundering’ are also particularly vague. It is therefore necessary to better reference and decipher these potentially criminogenic meeting points.

The overall objective is to achieve mapping that reflects the *spatial dynamics* of the most relevant risks. With this approach, it is easier to understand the types of criminal networks involved in this trafficking, as the concept of a network can “vary in size, form, membership, cohesion and purpose. Networks can be large or small, local or global, national or transnational, cohesive or diffuse, centralised or very decentralised...”³⁷⁷.

³⁷³ Sheila Brown, The criminology of hybrids, Rethinking crime and law in technosocial networks in David S. Wall, Crime and Deviance in Cyberspace, Ashgate, 2009, p. 27.

³⁷⁴ Source: the article by Carlo Morselli, Mathilde Turcotte and Guillaume Louis, “Le crime organisé et les contre-mesures” in Maurice Cusson, Benoît Dupont and Frédéric Lemieux (dir.), Traité de sécurité intérieure, Presses polytechniques et universitaires romandes, 2008, p. 186.

³⁷⁵ Valérie November, “Le risque comme objet géographique”, Cahiers de géographie du Québec, vol. 50, No. 141, 2006, p. 291.

³⁷⁶ Valerie November, “Being close to risk. From proximity to connexity”, International Journal of Sustainable Development, vol. 7, No. 3, 2004, p. 275.

³⁷⁷ Peter Grabosky, Michael Stohl, *Crime and terrorism*, Sage Publications, 2010, p. 80.

The analysis of networks would distinguish “strong ties and weak ties” within a network.³⁷⁸ But paradoxically, weak links are potentially significant because they extend a personal network and most importantly make it possible to go beyond this small circle to join other circles. It is therefore important to always try to analyse or map the nature of these links and the ability of certain operators to transform weak ties into strong ties even temporarily.

In other words, above all the idea is to have a better understanding of how the network works (“net-work” or rather “work-net” in the words of researcher Bruno Latour³⁷⁹). This dynamic view of the risks (associated with counterfeit drugs) should therefore favour a *navigational* approach³⁸⁰ to existing networks and their operation methods. These navigational practices may include new features such as foresight or feedback.³⁸¹

In addition, a *dynamic analysis* of the criminal organisations involved in counterfeiting is essential because criminal organisations can play on the multiple effects of spatial movements (changes in production sites, changes in transportation flows, etc.) and they master the different aspects of the “liquid society” referred to by Zygmunt Bauman³⁸². With such a conceptual approach (criminogenic interstices, meeting points, network navigation) it could be appropriate to attempt to gather statistics on specific areas. Specific areas could be assessed quantitatively according to local constraints like the hot spots³⁸³ in New York’s high-risk neighbourhoods. It is essential to encourage law enforcement agencies to “think outside the box, to gather information at the right time to analyse it quickly” because analyses can no longer be performed solely on the basis of field experience³⁸⁴ or frozen statistics. While compiling statistics on high-risk areas will be difficult to implement on an international scale, more dynamic and sophisticated mapping, in addition to its analytical advantages, would also help to rally the most motivated authorities and would help to influence and guide public actions³⁸⁵.

Without mapping techniques combined with a vulnerability model, it is difficult for an outside observer to perceive any strategy behind the flow of counterfeit medicines that appear to be predominantly opportunistic and thrive in areas where effective state presence is a problem (either lacking or is ambiguous, such as in Russia or China). Dynamic mapping, with updates of the most strategic risk areas, would make it easier to monitor these networks, decipher the logic behind criminal trends and propose scenarios to be able to foresee these trends.

That said, it is also important for these mapping methods to make use of a wider variety of social sciences.

³⁷⁸ Mark Granovetter, “The Strength of Weak Ties: A Network Theory Revisited”, *Sociological Theory*, vol. 1, 1983, p. 201-233.

³⁷⁹ Bruno Latour, *Changer la société, refaire de la sociologie*, La Découverte Poche, 2007, p. 208.

³⁸⁰ Valerie November, Bruno Latour, Eduardo-Hübner “Entering a risky territory: space in the age of digital navigation”, *Environment and Planning D: Society and Space*, vol. 28, No. 4, 2010, p. 594.

³⁸¹ Valerie November, “Being close to risk. From proximity to connexity”, *International Journal of Sustainable Development*, vol. 7, No. 3, 2004.

³⁸² Also see Zygmunt Bauman, *La vie liquide*, Editions du Rouergue, 2006.

³⁸³ Hot spots refer to criminogenic neighbourhoods. Updated statistics on these areas are used to map risks and help police regularly assess the situation and steer their actions. The technique was popularised in New York City.

³⁸⁴ Laurent Borredon, “Entretien avec Victor Goldsmith, professeur à la Pace University de New York”, *Le Monde*, September 13, 2012.

³⁸⁵ Bernard Debarbieux, Martin Vanier, *Ces territorialités qui se dessinent*, La Tour d'Aigues, Editions de l'Aube/Datar.

- The importance of greater support from social sciences

Traditional criminology remains related to social sciences such as law, psychology and sociology³⁸⁶ but in our area of study these theoretical approaches are rapidly limited, especially when criminal analysis is purely transgressive or marginal. In actual fact, crime should be considered from a benign and ordinary perspective³⁸⁷ and it is important to make use of other expertise in humanities that is often overlooked in criminological methods³⁸⁸: economics, demographics, geography, urban planning, etc.

With a “dynamic criminal network”, criminology must make use of international relations in particular³⁸⁹. Indeed we have seen how much regional conflicts and their links with certain grey zones (free trade zones) or strategic industrial zones (Chinese factories) can have an effect on trafficking of counterfeit medicines. It is therefore necessary to solicit researchers to decipher the “inconspicuous risks” and “combine territorial geopolitics with network geopolitics. Unlike governments, these criminal organisations cannot control large areas (...). In this respect, it should be noted that unlike government territoriality, the territoriality of large criminal organisations is not global, it is segmented”.³⁹⁰

It is essential to focus just as much on how the crime *is committed* in these “segmented territories” and on the conditions that may lead to the criminal act as on the actual criminals themselves.³⁹¹

To better understand the nature of these criminal networks it is no doubt also important to solicit research in gender studies³⁹². This academic discipline is not used to its fullest potential in criminology³⁹³ and although crimes are committed predominantly by men, the role of women has not been studied adequately in this area of research. A reminder that in the case of Kevin Xu (p. 59), the investigators were largely able to catch the Chinese businessman through his wife, and in the vast Middle East network that we have described, it was thanks to the Chinese wife of a Jordanian that a Chinese network was created and able to play a strategic part in the distribution of counterfeit medicines. In Egypt, Suzanne Mubarak³⁹⁴, wife of former President and a breast cancer victim, was sensitive to issues related to the criminal aspects of medicine counterfeiting. Through her influence, the Egyptian government incited General Mostafa Amr, former head of the Narcotics Bureau, to fight against this trafficking. Note also that there is a wide female presence in the medical and pharmaceutical sector and we have seen a network of pharmacies in France headed up in part by a Chinese woman that was involved in a network of counterfeit medicines.

³⁸⁶ Ronald V. Clarke, “Technology, Criminology and Crime Science” in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 444.

³⁸⁷ David Garland, *The Culture of Control: Crime and Social Order in Contemporary Society*, University of Chicago Press, 2001.

³⁸⁸ Ronald V. Clarke, “Technology, Criminology and Crime Science” in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 444.

³⁸⁹ Alain Bauer, *A la recherche de la criminologie : une enquête*, CNRS éditions, 2010, p. 37.

³⁹⁰ Jean-François Gayraud, François Thual, *Géostratégie du crime*, Odile Jacob, 2012, p. 86.

³⁹¹ Ronald V. Clarke, “Technology, Criminology and Crime Science” in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 445.

³⁹² Field of academic study concerning the issue of sexual gender and social difference observed between the biological sexes. Source: <http://www.e-marketing.fr/Definitions-Glossaire-Marketing/Gender-Studies-7853.htm>
Its application to criminology would mainly involve greater recognition of the female ‘gender’ in the development of criminal devices.

³⁹³ Paul Rock, “Sociological Theories of Crime”, 2002 in Mike Maguire, Rod Morgan and Robert Reiner (eds.), *The Oxford Handbook of Criminology*, Oxford University Press, 2007, p. 35.

³⁹⁴ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 220.

As we can see, it is important to diversify analysis methods to better understand the complexity of criminal networks.

- The importance of cross-disciplinarity and a novel perspective

It is also important that criminologists avoid focusing too much on a historical approach to criminology as modern-day crimes are often committed at high speed and therefore require faster and innovative crime analysis with a very operational dimension. This operational aspect also implies that criminologists have greater proximity with the private sector, while many of them are refractory to more coordination with the police and private security operators.³⁹⁵ The case of French-speaking Europe is quite specific when compared with Quebec where criminological researchers have diverse backgrounds and are closer to the police community. In France “research is based more on a sociological and criminological perspective that is *critical* of the police, *rather than in partnership* with the police”.³⁹⁶

A more pragmatic approach less focused on the legal and “idealistic” aspects of criminology would require more private sector operators or hybrid operators (NGOs) to be solicited, which makes the theoretical field of criminology more complex than before.³⁹⁷ One may also wonder whether the expertise called upon, particularly the police or former police officers working for pharmaceutical companies, should not benefit more from outside experts in their investigations.

A partnership with pharmaceutical researchers would be appropriate provided that it were not limited to scientific techniques testing the counterfeit nature of the medicines. In this respect, the researchers at Michigan University’s criminology centre³⁹⁸ working in pharmaceuticals and social sciences from a criminological perspective provide a fresh and relevant approach and should allow a better understanding of the new specific issues in connection with pharmaceutical crimes.

The novel and, to say the least, imaginative activities of these counterfeiters are quite a challenge for the police and its well-established techniques. In this respect, the Internet has revealed novel criminal activities requiring transnational investigations and where there is deviant conduct not generally considered by the police as strictly criminal.³⁹⁹ An excessively ‘routine’ perspective can facilitate but also predetermine police work in cases that will help it to take a stand that will structure the way the ‘criminal’ cases in question are perceived and considered.⁴⁰⁰ On a more operational level there is the case of the security director at a pharmaceutical company (which does not wish to be named) who feels that medicine counterfeiting organisations that can be truly called criminal are ones connected with traditional criminal circles (organised crime, drug traffickers, etc.). However, it is reasonable to wonder whether such an assumption is not likely to lead to major cases being overlooked in investigations when they are harder for this former police officer to identify due to their unconventional nature.

³⁹⁵ Ronald V. Clarke, “Technology, Criminology and Crime Science” in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 446, 447.

³⁹⁶ Martine Pattyn, Paul Wouters, “Définir des priorités en matière de criminalité”, in Maurice Cusson, Benoît Dupont and Frédéric Lemieux (dir.), *Traité de sécurité intérieure*, Presses polytechniques et universitaires romandes, 2008, p. 358.

³⁹⁷ Benoît Dupont, “Security in the Age of Networks” in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 572.

³⁹⁸ Anti-Counterfeiting and Product Protection Program, Michigan State University, <http://a-cappp.msu.edu>

³⁹⁹ David S. Wall, *Cybercrime. The Transformation of Crime in the Information Age*, Polity Press, 2007, p. 163.

⁴⁰⁰ Clifford D. Shearing, Richard V. Ericson, “Culture as figurative action”, *British Journal of Sociology*, vol. 42, No. 4, 1991, p. 481-506.

Generally, in our globalised world, it is important to move from conventional thinking to counter-intuitive thinking⁴⁰¹ as:

- Strategically, the most obvious dangers are not necessarily those that need to be prioritised.
- Well-intentioned efforts to fight against transnational criminal organisations (such as national or international treaties to counter illegal activities) can often have the opposite effect to the one expected and encourage criminal networks to simply adapt their strategy.
- The increasingly widespread values of material success and moral relativism mean that each individual may potentially be seduced by large and fast profits and participate directly or implicitly in such transnational criminal organisations.

These three points illustrate the competitive advantages enjoyed by transnational criminal networks in the current context. It is crucial to consider the possibility that national organisations and authorities do not have sufficient resources to stop such a criminal threat as criminals continuously defy slow, centralised, state-run organisations with their asymmetric and flexible methods. To sum up, these criminal organisations also use the *networks* in a much more appropriate and effective way than the law enforcers⁴⁰², which gives them an advantage in terms of speed and efficiency.

- A desire for anachronistic secrecy?

One may wonder, however, if the failure to solicit enough external researchers is the result of a desire for secrecy, given the very discrete nature of the pharmaceutical companies' investigations. This high level of discretion is justified in part because "a system of objective power (...) may quite legitimately operate in secret through its formal autonomy, without sacrificing its "publicity" for the purpose of defending everyone's interests. There is therefore no *logical* connection leading one to deduce that publicity has a greater value".⁴⁰³

We must also recognise that some counterfeiting areas are particularly difficult to access and that the 'secrecy' is partly due to the impenetrability of areas harbouring counterfeit medicines. Regarding this, a distinction can be made between "grey zones"⁴⁰⁴, where licit and illicit trafficking are intertwined (free trade zones, digital servers, tax havens, etc.) and "white zones" that do not appear on official maps and may concern trafficking of illicit medicines, particularly in connection with certain Russian and Chinese military zones. Lastly, there are Chinese industrial areas that are difficult to access or hazardous: these include north-east China, in particular Harbin, a city of five million inhabitants, where few foreigners travel to and considered a strategic region for medicine counterfeiting.⁴⁰⁵

It appears that many areas where counterfeit medicines are manufactured or transited are impossible or difficult to access⁴⁰⁶. In many cases access to information is difficult for all those involved and this 'secrecy' is not entirely deliberate. While it is also evident that ongoing investigations require full discretion, this desire for secrecy also seems to have reached its limits. The analysis of cybercrime clearly shows that credible and visible

⁴⁰¹ Robert Mandel, *Dark Logic, Transnational Criminal Tactics and global security*, Stanford Security Studies, Stanford University Press, 2010, p. 172.

⁴⁰² Mette Eilstrup-Sangiovanni, "Transnational networks and New Security Threats", *Cambridge Review of International Affairs*, vol. 18, No. 1, April 2005, p. 7-13.

⁴⁰³ Georges Simmel, *Sociologie, Etudes sur les formes de socialisation*, PUF, 1999, p. 372.

⁴⁰⁴ Gaïdz Minassian, *Zones grises. Quand les Etats perdent le contrôle*, Autrement, 2011.

⁴⁰⁵ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 183.

⁴⁰⁶ *Ibidem.*, p. 59.

sources exist, especially on the Internet, to decipher the challenges and even the criminals involved in such trafficking. Indeed, we have seen to what extent a simple blogger based in the United States, Brian Krebs, was able to relay valuable information on (Russian) criminal networks involved in medicine counterfeiting. Lastly, as the Wikileaks case showed on a wide scale, even confidential diplomatic information can be widely spread over the Internet. A CREDOC study⁴⁰⁷ confirms this trend, especially for the younger generation. “All this generation hears about is a society of information and new communication technologies, a knowledge-based economy (...).What it wants, above all else, is the language of truth, honesty”.

Several factors therefore ‘weaken the secrecy’ especially as, according to Simmel, “secret society is the right form for content that is somewhat in its infancy, with the vulnerability specific to the early stages of development”⁴⁰⁸, which brings us to wonder about this discretion in the medium term, which will lose its relevance in the event of a major health scare in the context of counterfeit medicine trafficking.

- The importance of the victims

Analysing medicine counterfeiting therefore implies taking into account the impact of this crime on victims and society, which has long been a blind spot for criminological analysts⁴⁰⁹ that pharmaceutical crime has acutely revealed.

Since the work of the German criminologist von Hentig⁴¹⁰, criminological approaches tend to show that the victim and criminal are often in direct contact. However, in our area of study there is actually a strong tendency for direct links between criminal and victim to disappear because in both ‘real’ networks and on the Internet the counterfeiters’ aim is to remain anonymous, thus artificially diluting the chain of responsibility. Another particularity described by the OECD⁴¹¹: “medicine counterfeiting has been described as the perfect crime because, if the patient's condition improves, there is no investigation, and if the patient's condition worsens, it will be primarily attributed to the patient's medical condition”. The link between the fact that the medicine is counterfeit and its effects on the patient are not always that obvious to observe or analyse. Therefore, it would also be appropriate to develop varied expertise to better identify and assess such victimisation.

In addition, as Edwin S. Sutherland stated in his reference work⁴¹², victims are rarely in a position to fight against the businesses involved in white-collar crimes. It is therefore essential in medicine counterfeiting for institutional and/or private stakeholders to relay accurate information on these medical risks to consumers. At operational level it is no doubt easier to conduct ‘victimization’ investigations in the context of international trade rather than in China itself.⁴¹³

⁴⁰⁷ CREDOC, “Effets de générations, d’âge et de revenus sur les arbitrages de consommation”, *Cahier de recherche*, No. 258, December 2008.

⁴⁰⁸ Georg Simmel, *Sociologie, Etudes sur les formes de socialisation*, PUF, 1999, p. 380.

⁴⁰⁹ Ronald V. Clarke, “Technology, Criminology and Crime Science” in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 444.

⁴¹⁰ Hans Von Hentig, *The Criminal and his Victim*, New Haven, Yale University Press, 1948.

⁴¹¹ OECD, *L’impact économique de la contrefaçon et du piratage*, Paris, 2007, p.102.

⁴¹² Edwin H. Sutherland, *White Collar Crime, The Uncut Version*, New Haven and London: Yale University Press, 1983, p. 237.

⁴¹³ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 187.

III.2. Considerations to counter this phenomenon

In this last part we will analyse different ways to gain better control over this phenomenon. The issues of analysis, intelligence, police work and expertise will be broken down in particular.

III.2.a. The issue of assessing the 'crime – counterfeit medicines' combination

This question arises in particular with regard to the reliability of the statistics announced. In terms of danger, the record often reported of 192,000 deaths due to the consumption of counterfeit drugs in China in 2001 should have been further verified and confirmed when it was simply relayed by most researchers and the media (particularly in 2002 by the *San Francisco Examiner*⁴¹⁴), and did not cause health authorities to sound the alert.⁴¹⁵ This lack of statistical stringency in such a major case of counterfeiting was identified by researchers at Oxford University, who noted in 2007 that a rough translation by a Chinese teacher for the *Shenzhen Evening News* created a misunderstanding over the actual extent of the problem. Indeed, the figure of 192,000 deaths did not relate directly to the counterfeiting of medicines, but more generally to diseases caused by these medicines and their misuse⁴¹⁶. It is therefore important to be more stringent when reporting these statistics and to better understand the real danger of counterfeit medicines and their impact. It would be useful to regularly publish reports and studies on the health effects of counterfeit medicines as this data is too scarce. More credible validated statistics are essential⁴¹⁷ for the credibility of public debate.

In terms of crime, it is also important to change existing analysis methods. Generally, law enforcement policies on transnational crime assess the success of operations based on the following criteria⁴¹⁸:

- A decrease in violence and corruption.
- The capture of criminal organisation leaders.
- A decrease in the size of these transnational criminal organisations.
- A decrease in their scope of operations.

However, these parameters are soon limited and can be poor indicators of crime prevention: the violence may decrease but the corruption increase, criminal leaders can become martyrs and be quickly replaced and success in one geographic area may mean that there is an increase in the same trafficking in another area.

In the fight against medicine counterfeiting, the situation is assessed primarily based on seizures or arrests but again these assessments can be guided by a policy to focus on seizures in certain regions or at certain times. In this respect, there has been a significant crackdown on the Internet.

⁴¹⁴ Martin Fackler, "China Fake Drugs Kill Thousands", *San Francisco Examiner*, July 29, 2002.

⁴¹⁵ Ibidem.

⁴¹⁶ Paul N. Newton, Robert Cockburn and Nicholas J. White, "Letter to the editor", *PLoS Medicine*, April 17, 2007.
<http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040289>

⁴¹⁷ Michele Forzley, *Counterfeit goods and the Public's Health and Safety*, International Intellectual Property Institute, July 2003.

⁴¹⁸ Robert Mandel, *Dark Logic, Transnational Criminal Tactics and global security*, Stanford Security Studies, Stanford University Press, 2010, p. 176.

For example, the Interpol's Pangea V operation from September 25th to October 2, 2012⁴¹⁹ resulted in:

- 79 arrests and the seizure of 3.75 million potentially deadly medicines worldwide worth a total of USD 10.5 million.
- The closure of 18,000 illegal online pharmaceutical websites.
- A global operation involving 100 countries.

In France this operation led to⁴²⁰:

- 427,000 smuggled and counterfeit medicines being seized by customs.
- 236 illegal sites offering medicines being identified.
- 14 suspect hearings, searches and seizures of computer equipment to investigate and pursue inquiries.

In comparison, Pangea IV in 2011⁴²¹ led to the arrest of fifty-five people, the seizure of 2.4 million doses of counterfeit medicines sold on the Internet and customs cooperation in 81 countries. We are therefore seeing an increase in seizures from one year to the next. However, although these initiatives are beneficial, accurate information on the current situation but more importantly on the impact of and follow-up to such operations is lacking, especially regarding the type of websites closed down and their ability to re-appear later on.

The issue of follow-up and the impact of such operations on the Internet was even more vital in the case of the "CyberChase Operations" initiative in April 2005⁴²² to crack down on illegal online pharmacies that distributed mainly steroids and amphetamines without a prescription. This operation, prepared over one year by the U.S. DEA (Drug Enforcement Administration) in partnership with agencies in other countries (Australia, India, Canada, Costa Rica) resulted in the arrest of 20 individuals in eight cities and the seizure of 41 bank accounts with a total value of USD 6 million. The initiative targeted the 'Bansal Organization' which had been operating since 2003 through 200 websites distributing some 2.5 million doses of medicine per month. Although this initiative was able to dismantle a major trafficking network, one wonders how effective such a method is. According to the researcher Bryan A. Liang, the main hurdle with this type of approach is the fact that conventional methods are used in the hope of reducing supply based on a primarily judicial approach. However, such a tactic based on laws targeting unconventional criminals difficult to intercept, due to their mobility and their mastery of technology, can be costly in terms of human resources when conducting investigations and prosecuting criminals. Are these operations assessed properly, particularly the financial aspects? Are they primarily just a show for the media? Are these operations too specific and limited in time? Is a medium-term review possible? These are all legitimate questions that are virtually absent from public debate.

The problem of assessing such crackdowns is also found in the 'real' world. For example, the strategies of multinationals to close counterfeiting plants can quickly reach their limits and have a boomerang effect as these initiatives may paradoxically encourage the most skilful Chinese counterfeiters to produce greater quantities at

⁴¹⁹ Interpol, Press release, *Global crackdown on illicit online pharmacies*, October 4, 2012.

⁴²⁰ ANSM, Press release, *Opération Pangea V : Lutte contre les réseaux de vente illicite de médicaments sur Internet*, October 4, 2012.

⁴²¹ The operation took place September 20 to 27, 2011. Sources: National Gendarmerie and liberation.fr, "Médicaments contrefaits sur Internet : saisie de 2,4 millions de doses dans le monde", *Libération*, September 29, 2011.

⁴²² Bryan A. Liang, Tim Mackey, "Searching for Safety: Addressing Search Engine, Website, and Provider Accountability for Illicit Online Drug Sales", *American Journal of Law and Medicine*, vol. 35, No. 1, 2009, p. 125-184.

the start of the production cycle to offset these anticipated losses.⁴²³ Therefore, raids might not stop Chinese manufacturers from returning to the business, even more motivated, just weeks after the plants have closed.⁴²⁴

In light of such “creative and unconventional” criminal organisations, particularly in China⁴²⁵, or more generally with “criminal markets that operate in a disorganised way and characterised by multiple actors working together in complex and unpredictable ways forming loose alliances”⁴²⁶, it is also important to renew law enforcement assessment methods. Although it certainly seems necessary to assess the success of crime prevention based on *management criteria*⁴²⁷, these criteria should be specified and not be limited to mere seizures.

These management criteria include assessments with a regular review of cases handled, senior staff at both operational level and in intelligence, analysing international partnerships, training abroad, etc. In other words a whole range of measures that are by no means limited to mere seizures and that, as we have seen, must be specified and contextualised more. With regard to criminal organisations, it is mainly important to have a selective approach to crime prevention by adapting crackdowns on different time scales based on the complexity of the case.

How can intelligence be conceived and organised in such a context?

III.2.b. Improving the analysis of the problem through centralised intelligence

Too often observers (researchers, seasoned journalists, etc.) only have access to standardised information or more credible but scattered information. It is therefore essential to find alternative analysis methods rather than prolonging existing methods to achieve the selective hierarchical centralisation of information in ‘pharmaceutical counterfeiting crime’.

What’s more, online cybercrime is no doubt easier to decipher than crime in the ‘real’ world. “Although it does not actually foster a sharp increase in counterfeiting, the digital world supports the growth of an economy of copying and falsification, paradoxically less ‘underground’ as it is visible across the planet”.⁴²⁸ It is therefore important to continually improve the increasingly centralised online watch but moreover to better track criminal networks in the ‘real’ world both in terms of interactions between the actors involved and also their local form.

Intelligence efforts should be made not only to dismantle networks, which is usually complex and time-consuming, but also to steer the impact of the crimes towards victims and society, something that traditional criminology has for too long neglected to do.⁴²⁹ In actual fact, criminal intelligence should make a qualitative leap⁴³⁰, given the new forms of organised crime emerging, and not narrow its perspective by simply assisting

⁴²³ Daniel C. K. Chow, “Anticounterfeiting Strategies of Multinational companies in China: How a flawed approach is making counterfeiting worse”, *Georgetown Journal of International Law*, vol. 41, No. 4, summer 2010.

⁴²⁴ Ibidem.

⁴²⁵ Ming Xia, “Organizational Formations of Organized Crime in China: perspectives from the state, markets, and networks”, *Journal of Contemporary China*, vol. 17, No. 54, 2008, p. 1-23.

⁴²⁶ Council of Europe, Organised crime situation report, 2001.

⁴²⁷ Robert Mandel, *Dark Logic, Transnational Criminal Tactics and global security*, Stanford Security Studies, Stanford University Press, 2010.

⁴²⁸ Eric Schmidt (dir.), CEIS, Evaluation de l’ampleur de la vente des produits contrefaisants sur internet, March 2009.

⁴²⁹ Ronald V. Clarke, “Technology, Criminology and Crime Science” in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 444.

⁴³⁰ François Farcy, Jean-François Gayraud, *Le renseignement criminel*, CNRS éditions, 2011, p.23.

criminal investigation.⁴³¹ This emphasis on intelligence can also be found at European level in: *The EU Internal Security Strategy. Towards a European Security Model*⁴³², which defines organised crime as one of the main threats to the EU alongside terrorism and stresses the importance of anticipation and intelligence. Through a recent report by the National Security Council, *Strategy to Combat Transnational Organized Crime*⁴³³, the United States also insisted on this aspect of intelligence, distinguishing between “substantially upgraded signals intelligence” (SIGINT), “human intelligence” (HUMINT) and “open sources intelligence” (OSINT). The first two forms of intelligence are, according to this US report, essential in the fight against transnational criminal organisations. That said, open intelligence should not be neglected and it is currently too scattered as far as medicine counterfeiting is concerned.

Generally, the main idea is to have a collaborative approach⁴³⁴, helped by the fact that the Internet is by definition an interactive tool. Government agencies cannot fight against this phenomenon alone⁴³⁵ and it is essential to involve private actors (companies but also NGOs) in implementing a policy to centralise intelligence. It is also important to develop cross-sectoral approaches. For example, pharmaceutical manufacturers could draw inspiration from the cosmetics sector. Monitoring should also be organized horizontally in terms of skills, with a variety of social science approaches, rather than focusing reductively on criminology. According to sociologist Howard S. Becker⁴³⁶, an act becomes deviant primarily depending on interaction with others. This concept of crime is very relevant in a world organised in networks where the line between lawful and unlawful is increasingly crossed by many actors and opportunistic individuals often unfamiliar with mafia groups or any other major criminal organisation.

As the National Security Council report suggests, effective intelligence could also help develop profiles of individuals, companies and institutions connected to these transnational criminal organisations. As for the individuals involved in counterfeiting crime, it would be useful to better understand their psycho-sociological profile and the conditions that lead such actors to go against social norms. Greed is certainly an obvious motivation but it is often an insufficient explanation. Medicine counterfeiting is a major criminal area that warrants more centralised intelligence and research on the profile of the criminals involved. The financial sector sets a good example with the Behavioral Analyst Unit (BAU), a section of the FBI that became involved in white-collar crime after the Madoff affair. One year after the American embezzler was discovered, the FBI opened the BAU-2, “a special unit of eight federal officers whose mission is to profile the psyche of this new category of serious financial criminals”.⁴³⁷ The profile of financial criminals is even more complex to decipher than serial killers and according to Mark Hiltz, head of the BAU-2, it will take several years before “being able to achieve any accurate criminological characterization of this type of offender”.⁴³⁸ However, greed does not appear to be the mainspring of these financial criminals but rather fantasies of omnipotence supported by a psychological process of lies and denial. One may wonder whether this rigid logic of denial is found in certain serious criminals involved in major cases of medicine counterfeiting. The case of Andrew Strempler is revealing in this respect as he often claimed to be a ‘white knight’ fighting against the monopoly of pharmaceutical companies, which no doubt helped to nurture his denial regarding his illegal activities. One particularity for a significant portion of white-collar criminals involved in medicine counterfeiting seems to be that they do not see themselves as

⁴³¹ *Ibidem.*, p.37.

⁴³² Publications Office of the European Union, *Stratégie de sécurité intérieure pour l’Union européenne. Vers un modèle européen de sécurité*, 2010.

⁴³³ National Security Council, *Strategy to Combat Transnational Organized Crime*, July 25, 2011, p. 17.
<http://www.whitehouse.gov/administration/eop/nsc/transnational-crime>

⁴³⁴ A.T. Kearney, Grocery Manufacturers Association, *Consumer Product Fraud: Deterrence and Detection*, 2010, p. 18.

⁴³⁵ *Ibidem.*

⁴³⁶ Howard S. Becker, *Outsiders, Etudes de sociologie de la déviance*, Métailié, 1985.

⁴³⁷ Jean-Marie Hosatte, “Wall Street sous l’oeil du FBI”, *Le Monde Magazine*, August 27, 2011.

⁴³⁸ *Ibidem.*

criminals⁴³⁹. Some, on the other hand, like Strempler, are perfectly comfortable with the view of the “white-collar criminal” dear to criminologist Donald Cressey and use “verbalization which enables them to commit their crime while maintaining an ideal of honesty”⁴⁴⁰. The importance, according to Cressey, of how white-collar criminals are motivated and justify their crimes is food for thought that warrants more specific research in the area of medicine counterfeiting.

The central involvement of pharmaceutical companies in investigations, the complex impact of the effects of medicine counterfeiting and the sophistication of the supply chain can support their claims. It would therefore be appropriate to thoroughly analyse the profiles of these criminals to be better equipped to counter their often false claims. At the very least it would be useful to understand the reasoning and behaviour of the different types of criminals involved in medicine counterfeiting to help guide law enforcement.

It is therefore important to encourage centralised intelligence not limited solely to the criminal underworld but also focusing on contextual aspects (e.g. geopolitical), industrial aspects (monitoring supply chain organisation⁴⁴¹) and even psycho-sociological aspects that can lead to illegal trafficking of medicines. Lastly, it is essential to have intelligence activities in foreign markets⁴⁴² and in this context security officers and embassy diplomats could be mobilised to decipher such risks particularly by monitoring border areas.

But in addition to useful intelligence there is the more general issue of law enforcement in such a context.

III.2.c. The issue of law enforcement

The law enforcement challenge raises two issues: the first concerns the meaning of ‘policing’ and the second the way law enforcement is implemented.

- ‘Policing’

Some researchers question ‘policing’ in the global and repressive sense. Indeed, regardless of policing innovations, in general the tasks of the police force remain fundamentally limited. As demonstrated by sociologist Michael Lipsky almost thirty years ago⁴⁴³, “the number of problems the police has to deal with is so great that its resources could be forever increased without its needs ever being met”.⁴⁴⁴ Indeed, transnational illegal activities currently come under a web of global interconnections with low-cost transportation and communication and are “unstoppable”.⁴⁴⁵ A general viewpoint that could be applied in part to counterfeit medicines for law enforcement agencies given that so many cases appear to be uncontrollable on a global scale, in particular in developing and emerging countries.

⁴³⁹ A view similar to that of Sutherland, who addressed this point of view in general terms, but can be applied to the specific case of white-collar crime in medicine counterfeiting. Edwin H. Sutherland, *White Collar Crime, The Uncut Version*, New Haven and London: Yale University Press, 1983, p. 230.

⁴⁴⁰ Donald Cressey, *Other's people money*, Belmont, CA: Wadsworth, 1953, p. 142.

⁴⁴¹ World Economic Forum, *Global Risks*, Sixth edition, An Initiative of the Risk Response Network, 2011, p. 24.

⁴⁴² Federico Varese, “Mafia movements: a framework for understanding the mobility of mafia groups”, *Global Crime*, vol. 12, No. 3, 2011, p. 218-231.

⁴⁴³ Michael Lipsky, *Street-Level Bureaucracy*, New York, Russell Sage Foundation, 1980.

⁴⁴⁴ Mathieu Zagrodzki, *Que fait la police ? Le rôle du policier dans la société*, Editions de l'Aube, 2012, p. 92.

⁴⁴⁵ Robert Mandel, *Dark Logic, Transnational Criminal Tactics and global security*, Stanford Security Studies, Stanford University Press, 2010, p. 7.

How can 'policing' be defined in this context?

Essayist Luc Boltanski stated in a recent original work⁴⁴⁶ that "as state agents, the police only has as much power as it is given by the state, i.e. that of any ordinary police force, within the framework of the law. This power is sufficient to capture common criminals (...), but insufficient when it comes to defeating elite criminals. Police officers know only the reality of their official determination". Is this comment pessimistic or realistic? In any case it has the merit of showing the boundaries of conventional police methods in such a complex, global and unique area as medicine counterfeiting. This police expertise is especially limited when it comes to certain countries. While the Chinese and Russian governments may appear dubious to say the least, the case of North Korea, which has apparently specialised in counterfeit cigarettes, currency and medicines, including Viagra labelled 'Made in USA'⁴⁴⁷, is an example in the extreme proving that, in certain countries, even the best experts will have a limited scope of intervention and limited intelligence.

In this context, the work of the police (or customs) is more like detective work: "(...) because they have the same intelligence and the same perversity as serious criminals, they too are able to dig into the cracks and interstices of reality to exploit incoherencies, which may also mean to the extent of revealing inconsistencies."⁴⁴⁸

This is detective work where, as we have seen, information is more than ever strategic, especially when found as early as possible, to anticipate the risk of counterfeiting.

- Law enforcement

To counter the networks that are the preferred organisation of these criminals, the strategies and measures should be maximised into law enforcement networks. These law enforcement networks involve a variety of actors whose contribution should not be too static.⁴⁴⁹ It is mainly important to have a selective approach to crime prevention by adapting law enforcement on different time scales based on the complexity of the case. As we saw with the Jordanian-Chinese network and the RxNorth case, crackdowns can take five, ten years, or more. In the era of the Internet and the spectacularly publicised staging of organised crime, it is important in law enforcement to focus on medium and long-term action, rather than media hype that is no doubt useful but at the very least approximate in terms of analysis and follow-up. Therefore rapidly dismantling truly transnational organisations must remain the priority when taking action and assessing this action. On this point, a working group devoted to medicine counterfeiting could be created based on the Threat Mitigation Working Group⁴⁵⁰, which is a U.S. interagency structure involving the main actors involved in transnational organised crime.

For major cases with a significant health impact but involving fewer actors, such as the Peter Gillespie case, there should be less focus on criminological monitoring and increased surveillance of the many pharmaceutical supply chain networks and sub-networks as this is where the greatest risk lies. A "law enforcement network" approach is therefore essential as is increased information-sharing between stakeholders. This approach must be rapidly available whenever necessary according to the criminal networks investigated. Although pharmaceutical company investigative departments have acquired this culture, it is less likely that more visible institutional agencies will have such a flexible organisation (with the notable exception of the MHRA). Yet this need for network-type organisation in law enforcement is not new. It was already the case in the Revco affair, a major pharmaceutical fraud concerning American Medicaid in the spring of 1977, where law enforcement

⁴⁴⁶ Luc Boltanski, *Enigmes et complots, Une enquête à propos d'enquêtes*. Gallimard, 2012, p. 59.

⁴⁴⁷ Peter Grabosky, Michael Stohl, *Crime and terrorism*, Sage Publications, 2010, p. 56

⁴⁴⁸ Luc Boltanski, *Enigmes et complots, Une enquête à propos d'enquêtes*. Gallimard, 2012, p. 59.

⁴⁴⁹ Benoît Dupont, "Security in the Age of Networks" in David S. Wall, *Crime and Deviance in Cyberspace*, Ashgate, 2009, p. 581.

⁴⁵⁰ National Security Council, *Strategy to Combat Transnational Organized Crime*, July 25, 2011, p.13.

agencies worked as an effective temporary network to pursue the protagonists.⁴⁵¹ This approach is widely neglected today.

One might also wonder whether it is the responsibility of multinational drug companies to replace the governing powers as far as public health is concerned. Certain investigators (who does not wish to be named) hint at the fact that their actions are limited. American researcher Daniel C. K. Chow is harsher on this subject and quotes the example of China, with which multinationals are generally overcautious when it comes to negotiations. These large companies have too much of a tendency to favour short-term action when it is essential to develop legal, political and social expertise to establish truly effective solutions. As for anti-counterfeiting and brand protection leaders, according to Chow they generally lack the skills and training to address such issues.⁴⁵²

An excessive view that our report does not validate, but which has the merit of highlighting the fact that certain enforcement actions could benefit from certain major adjustments. At operational level it is no doubt easier to conduct investigations in the context of international trade rather than in China itself.⁴⁵³

Ideally the crackdown on counterfeit medicines should be led by an international agency similar to Britain's MHRA that has the power to investigate and intervene and real organisational and territorial mobility (contrary to Interpol, which primarily coordinates different national law enforcement services). Whatever the qualities of the pharmaceutical company investigative departments, it is not their job to undertake global public health missions and it is therefore essential for the authorities in the main countries concerned get past certain controversies related in particular to intellectual property law or other legal issues to achieve this type of structure. Such an agency would also be consistent with the police policy known in eighteenth century Germany as *Polizeiwissenschaft*, aimed generally at "bringing happiness to its subjects" and "maintaining regulations that tend to make life comfortable".⁴⁵⁴ Specifically this policing was "designed to mark and improve its place in the rivalry and competition between European states and ensure internal order through the "well-being of individuals".⁴⁵⁵ In this case the idea would be to apply this European approach to an international police specialising in medicines or public health issues.

This strategic vision of trade control is confirmed by essayist Frédéric Gros according to whom the police must go "beyond the criminal or rebellious aspects, it is the life of the people, life as a fluid process that must be safeguarded".⁴⁵⁶

III.2.d. The issue of prevention

This prevention can be improved in two ways: firstly through better controlling market forces and secondly through increasingly intensive training for those involved in anti-counterfeiting.

⁴⁵¹ Diane Vaughan, *Controlling Unlawful Organizational Behavior: Social Structure and Corporate Misconduct*, The University of Chicago Press, 1985, p. 105.

⁴⁵² Daniel C. K. Chow, "Anticounterfeiting Strategies of Multinational companies in China: How a flawed approach is making counterfeiting worse", *Georgetown Journal of International Law*, vol. 41, No. 4, summer 2010.

⁴⁵³ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 187.

⁴⁵⁴ Michel Foucault, *Sécurité, Territoire, Population*, Cours au Collège de France, 1977-1978, Hautes Etudes, Gallimard, Seuil, 2004, p. 376.

⁴⁵⁵ *Ibidem*.

⁴⁵⁶ Frédéric Gros, *Le principe sécurité*, Gallimard, 2012, p. 144.

- Towards better control over market forces

Although we have seen to what extent the concept of criminal organisation takes on various forms, one wonders if “the groups themselves are less important than the markets in which they operate”.⁴⁵⁷ Political efforts should therefore “first and foremost interrupt market forces hidden behind this illicit trafficking. Breaking up each criminal group does not work, because every group arrested is immediately replaced (...). Tougher laws against mafia groups will not stop illegal activities if hidden markets remain unscathed”.⁴⁵⁸ “The groups themselves are less important than the markets in which they operate”.⁴⁵⁹

Control over market forces is particularly important and significant on the Internet. As stated by researcher John Richard Castronova⁴⁶⁰, law enforcement on the Internet no doubt focuses more on reducing demand than on “Cyber Chase Operations”-type activities, the effectiveness of which is increasingly limited, particularly as certain illegal online pharmacies are domiciled in countries where it is difficult to enforce the law. Prevention should therefore essentially involve consumer education and giving legal online pharmacies much greater visibility and value. Castronova feels that the prices of medicines in the United States could also be a decisive factor in American consumer choice, steering them towards illegal sites rather than supporting product safety. The solution therefore also involves information campaigns on the risks of purchasing specific products and giving greater value to existing legal pharmacies (which are VIPPS-certified and have low visibility). In developing countries the restoration of the rule of law is no doubt the most important strategic element as expert Roger Bate of the American Enterprise Institute and the UNODC recently recalled in an international crime report.⁴⁶¹ This issue of decreasing demand, today still undervalued on the Internet⁴⁶², is most likely strategic, but it should not, however, exclude crackdowns on major criminal networks.

- The issue of training anti-counterfeiting organisations

In order to reduce demand, training is essential. The many examples include the training of Nigerian NAFDAC⁴⁶³ agents by its U.S. counterparts, which is a step in the right direction. The same NAFDAC was then able to send agents to China and India to help the local staff to conduct counterfeiting tests on medicines collected by local authorities before they were shipped to Nigeria.⁴⁶⁴ A salutary initiative.

⁴⁵⁷ UNODC, *The Globalization of Crime, A Transnational Organized Crime Threat Assessment*, 2010, p. 29.

⁴⁵⁸ UNIS, Press release, “Organized Crime Has Globalized and Turned into Security Threat”, United Nations Information Service Vienna, June 2, 2010.

⁴⁵⁹ UNODC, *The Globalization of Crime, A Transnational Organized Crime Threat Assessment*, 2010, p. 29.

⁴⁶⁰ John Richard Castronova, “Operation Cyber Chase and Other Agency Efforts to Control Internet Drug Trafficking, The ‘Virtual’ Enforcement Initiative is Virtually Useless”, *Journal of Legal Medicine*, vol. 27, No. 2, 2006.

⁴⁶¹ Roger Bate, “Counterfeit Drugs and Internet Smarts; More public education would help stem the problem of fake pharmaceuticals-restricting Internet trade would not”, *The Wall Street Journal Online*, November 23, 2009.
UNODC, *The Globalization of Crime, A Transnational Organized Crime Threat Assessment*, 2010.

⁴⁶² A notice from the Council of Europe in 2007 stated: “The criticisms of the mail order sale of medicines relate primarily to the dangers arising from the illegal sale on the internet of medicines that may be counterfeit, but that the legal sale of mail order medicinal products is often forgotten”. Source: IRACM, *Endiguer la prolifération de faux médicaments sur le web*, January 30, 2012. A white paper from Cambridge Consultants also stresses the need to educate consumers in the purchasing of online medicines and to develop standards.

Cambridge Consultants, *Phony Drugs, Real Solutions: practical anti-counterfeiting consideration*, 2010.

⁴⁶³ NAFDAC: National Agency for Food and Drug Administration and Control (Nigeria). <http://www.nafdac.gov.ng/>

⁴⁶⁴ Roger Bate, *Phake: The Deadly World of Falsified and Substandard Medicines*, The AEI Press, 2012, p. 72.

One other example: in 2001 Pfizer set up a series of partnerships with the Chinese government⁴⁶⁵, an idea that should be developed. In 2004 the American company signed a partnership with the *Shanghai Municipal Food and Drug Administration* to detect and stop counterfeiting.⁴⁶⁶ Other agreements have followed and through these initiatives China has apparently been able to recover 600,000 packs of Viagra, 440,000 Viagra pills and 260 kilos of starting materials to produce counterfeit drugs.⁴⁶⁷

Having said that, better prevention and training on the distribution of counterfeit medicines must also be accompanied by whistleblowers and experts able to lead public debate in a more rational manner, especially on criminal issues.

III.2.e. The importance of whistleblowers and experts

Whistleblowers and new forms of expertise have a strategic role in the fight related to the “counterfeit medicines – crime” combination.

- Whistleblowers

It is important for approximate evaluations concerning counterfeit medicines to be put into perspective in public debate. For example independent journalists and researchers could work in the academic field or the media to question certain studies or to guide the debate towards areas that are being neglected. Our analysis appears to show that the current definitions of counterfeiting pay little attention to “communication, interaction or comparison arousing less interest in the media. These areas can be classified as “discrete areas” or “specialised areas”⁴⁶⁸. Chinese industrial estates specialising in counterfeiting, free trade zones, free ports, tax havens, “digital havens”⁴⁶⁹, companies relaying spam, Internet forums, etc. are surprisingly virtually absent from public debate. These areas are particularly strategic as “they can be considered as often the first or even the primary places where one finds the definitional processes that give problems, namely risks, their characteristics while determining how they exist. Hence questions about the importance and meaning usually given to the publicising phase”.⁴⁷⁰ It is also important to support “*local whistleblowers*”. In China, most cases of counterfeit drugs are reported by the media, and a personality like Gao Jingde⁴⁷¹, fighting the counterfeiters in his country, should be supported in his efforts. He noted in September 2008 that two-thirds of Chinese pharmacies sold counterfeit

⁴⁶⁵ Dina M. Bronshtein, “Counterfeit Pharmaceuticals in China: Could Changes Bring Stronger Protection for Intellectual Property Rights and Human Health?”, *Pacific Rim Law & Policy Journal*, vol. 17, No. 2, 2008.

⁴⁶⁶ Medical News Today, *Pfizer Signs Agreement with Shanghai Government to Enhance Protection of Patients*, May 19, 2004, <http://www.medicalnewstoday.com/articles/8476.php>.

⁴⁶⁷ Peggy B. Hu, Berta Gomez, “Public Safety Jeopardized by Chinese Counterfeiters, Experts Say”, *Washington File Staff Writers*, May 20, 2005. <http://wfile.ait.org.tw/wf-archive/2005/050520/epf508.htm>

⁴⁶⁸ Claude Gilbert, Emmanuel Henry, “Au-delà de la mise sur agenda. Les processus de définition des problèmes: enjeux-clés pour l’analyse de l’action publique”, *Congrès AFSP*, 2009.

⁴⁶⁹ A ‘digital haven’ can be defined as the hosting of illegal activities on computer servers without the risk of punishment.

Expression used by Solange Ghernaoui-Hélie, *La cybercriminalité : le visible et l’invisible*, Presses polytechniques et universitaires romandes, 2009.

⁴⁷⁰ Claude Gilbert, Emmanuel Henry, “Au-delà de la mise sur agenda. Les processus de définition des problèmes: enjeux-clés pour l’analyse de l’action publique”, *Congrès AFSP*, 2009.

⁴⁷¹ Roger Bate, Phake: The Deadly World of Falsified and Substandard Medicines, The AEI Press, 2012, p. 187.

medicines...⁴⁷². Strangely, even in 'authoritarian' countries like Syria, Egypt and China, there are visible or more discrete lobbyists. In Syria the medical training of Bashar al-Assad (Doctor in ophthalmology) and his cardiologist father-in-law in London contributed to raising the awareness of the Syrian government on certain law enforcement measures (ironically, in light of the current situation).

It is also essential to adapt information on networks involved in counterfeit medicines to the public (politicians, consumers, young internet users, etc.). Anthropologist Mary Douglas has shown how "the ways dangers are apprehended and ranked differ greatly depending on the structure of social groups and networks of special commitments which individuals have entered"⁴⁷³. This implies that the information should be adapted to the social group. Although this is not the place to debate communication policies vis-à-vis the general public on these issues, it may be noted that the most strategic whistleblowers are most likely found among healthcare professionals and policymakers. The latter appear too often to have delegated the issue of counterfeiting to external (public or private) organisations whose effectiveness should be further questioned as lobbying issues are sometimes confused with monopoly protection issues. In light of our previous thoughts on the importance of international coordination and the 'white-collar crime' aspect related to the pharmaceutical industry, it is important to better inform these 2 groups about the risks associated with medicine counterfeiting through well-dosed, targeted, and pragmatic information. It is important in some cases for these warnings to be fast, especially in crisis situations and the Internet offers many real-time mapping opportunities that are hardly used by stakeholders. This view, which may have its limits, would especially make it possible to make "the risks palpable" and thereby make the warnings of criminal threat "credible"⁴⁷⁴.

- Experts

Lastly, it is essential for some of these whistleblowers to also provide expertise, particularly by making visible what is not⁴⁷⁵. However, the current environment does not lend itself to this kind of initiative and pharmaceutical industry experts are often especially discrete in this area: even companies that specialise in the traceability of medicines do not wish to share information on this subject. This is probably due to a lack of independence as "it would appear that the high level of interaction today between these experts' sectors and the economic sectors (...) makes it increasingly problematic to remain 'outside the circle'. There are so many conflicts of interest that it becomes difficult to recruit experts who are both competent and have no ties with the issues they must analyse"⁴⁷⁶. It is particularly important for more economists to become involved in such topics, particularly organised crime, to decipher the illegal aspects of these networks, but also and especially their involvement in legal activities.⁴⁷⁷

In terms of expertise, it is also necessary to develop connections with the research community, particularly at an early stage, to anticipate problems. As we have seen in relation to the profile of criminal organisations in our area of study, work should not be limited to criminology research centres, which, in addition, are often not in

⁴⁷² *Ibidem.*, p. 188.

⁴⁷³ Yannick Barthe, Cyrille Lemieux, "Les risques collectifs sous le regard des sciences du politique. Nouveaux chantiers, vieilles questions", *Politix*, vol. 11, No. 44, 1998, p. 23.

⁴⁷⁴ Francis Chateauraynaud, Didier Torny, *Les sombres précurseurs. Une sociologie pragmatique de l'alerte et du risque*, éditions de l'EHESS, 1999.

⁴⁷⁵ Yannick Barthe, Cyrille Lemieux, "Les risques collectifs sous le regard des sciences du politique. Nouveaux chantiers, vieilles questions", *Politix*, vol. 11, No. 44, 1998, p. 17.

⁴⁷⁶ Yannick Barthe, Claude Gilbert, "Impuretés et compromis de l'expertise, une difficile reconnaissance. À propos des risques collectifs et des situations d'incertitude", in Laurence Dumoulin, Stéphane La Branche, Cécile Robert, Philippe Warin (dir.), *Le recours aux experts. Raisons et usages politiques*, Grenoble, PUG, 2005, p. 53.

⁴⁷⁷ Clothilde Champeyrache, *Sociétés du crime, un tour du monde des mafias*, CNRS éditions, 2008, p. 237.

touch with operational issues. What's more, it can be assumed, as indicated in a National Security report⁴⁷⁸, that the fight against the most complex transnational criminal organisations involves the use of more varied expertise from the industry, finances, academia, civil society and NGOs drawing on a greater number of varied partnerships.

Indeed, the use of other academic profiles (geography, economics, management, industrial risk specialists in the pharmaceutical industry, scientists) will enable traceability techniques to be developed for use in certain investigations to trace the sources. In a case of antimalarial medicine counterfeiting for example, a pollen analysis technique helped to identify the source of production of medicines counterfeited in southern China on the border with Vietnam, Laos and Myanmar.⁴⁷⁹ These investigations were coordinated by Interpol, WHO and Wellcome Trust, a medical research fund based in London. A certain type of pollen and calcite, a mineral from the Guangxi province, was specifically able to identify the suspect area. Armed with this information, the Chinese authorities were able to arrest Xu Qiang, a middleman in the Yunnan province. He used to sell legitimate pharmaceuticals but also became involved in illicit trafficking when he was approached by Burmese traders who wanted counterfeit medicines to sell them at a substantial profit.

In the emerging digital world it is unlikely that the experts in question will be found in the conventional criminological field as "criminology, which seems in an ideal position to apply its theories and methodological tools to analyse cybercrime, is struggling to understand the deviances found in the digital world"⁴⁸⁰. As for computer scientists, they tend to restrict their thoughts to the technical aspects and the societal aspects are often overlooked.

The research centre in Michigan⁴⁸¹, which combines criminological and pharmaceutical approaches, is a model that should undoubtedly be implemented in other countries. In terms of expertise, the creation of hybrid forums⁴⁸², aimed at co-producing knowledge, in particular through discussions between scientists (or engineers, researchers), and political action, is essential. It is therefore necessary for these forums to rapidly find fields of expression and for credible albeit sometimes patchy information to support their efforts as we have seen just to what extent approximate information can lead to problems in public debate. Generally speaking it is important to recognise the legitimacy of minority views⁴⁸³, which are particularly interested in strategic and undervalued areas of public debate which tend to be avoided by some individuals with professional expertise who seek to "keep their considerations pure".⁴⁸⁴

⁴⁷⁸ National Security Council, *Strategy to Combat Transnational Organized Crime*, July 25, 2011, p. 14.
<http://www.whitehouse.gov/administration/eop/nsc/transnational-crime>

⁴⁷⁹ Walt Bogdanich, Jake Hooker, "Battle Against Counterfeit Drugs Has New Weapon: Pollen", *The New York Times*, February 12, 2008.

⁴⁸⁰ "At the last annual American Society of Criminology conference (St. Louis 2008), which is the world's largest gathering of researchers in this field with nearly 2,000 participants, all papers on technological crimes, computer crimes and Internet-related crimes accounted for exactly 1% of all contributions".

Source: Benoît Dupont, Vincent Gautrais, "Crime 2.0: le web dans tous ses états !", *Champ Pénal : Nouvelle revue internationale de criminologie*, vol. 7, 2010.

⁴⁸¹ Anti-Counterfeiting and Product Protection Program, Michigan State University, <http://a-cappp.msu.edu>

⁴⁸² Yannick Barthe, Michel Callon and Pierre Lascoumes, "Réponse à Franck Aggeri", *Gérer et comprendre*, No. 68, June 2002.

⁴⁸³ Michel Callon, "Des différentes formes de démocratie technique", *Annale des Mines*, January 1998, p. 63-73.

⁴⁸⁴ Yannick Barthe, Cyrille Lemieux, "Les risques collectifs sous le regard des sciences du politique. Nouveaux chantiers, vieilles questions", *Politix*, vol. 11, No. 44, 1998, p. 26.

III.2.f. Internet specificities

It is important for law enforcers to really consider all the specificities of the Internet and we propose in this context four priorities for more effective law enforcement.

- A specific network

Given our previous thoughts on the Internet, many law enforcers appear to pay little attention to the actual way this digital network functions. It would be useful to better understand the particularities of counterfeiting on this virtual network before initiating enforcement measures. In fact, most of the challenges of counterfeiting on the Internet raise issues that go well beyond the concept of 'real or fake' products because "in a networked world the question of authenticity is no longer valid"⁴⁸⁵ and "the economic value is more related to *ideas* than to the physical ownership of goods or services".⁴⁸⁶ To summarize, in a largely post-industrial context, the *control over information* has become the central challenge rather than product counterfeiting in the strictest sense. In this society of information "it is crucial to know who receives the information, how and by what means, about whom and what and for what purpose they are sent"⁴⁸⁷. In addition, an object's value "does not stem from its rarity as it can easily be duplicated almost infinitely".⁴⁸⁸ The infinite nature of information over a network devoid of any centre or hierarchical governance introduces complex challenges for those involved in the fight against cybercrime. Indeed, conventional information, investigation and infiltration techniques are difficult to apply, to say the least, in such an environment and we have seen that the removal of sites specialising in counterfeit drugs is probably only a temporary solution.⁴⁸⁹ On the Internet the asymmetry between law enforcement authorities and the criminal is particularly strong and benefits the fraudster even more than in the 'real' world: "computer hackers have a choice of weapons while defenders have to consider all scenarios. (...) How is it possible to adhere to the sacrosanct principles of simultaneous and proportionate response for attacks that last a few milliseconds in an unpredictable environment?".⁴⁹⁰

As for anti-counterfeiting techniques proposed by companies such as MarkMonitor, which consist of "understanding both distribution channels and digital promotion vehicles to develop effective neutralization strategies"⁴⁹¹, they remain limited, to say the least, as online counterfeiting network strategies will always have the upper hand over these law enforcement techniques.

Lastly, radical solutions such as filtering are technically questionable⁴⁹² and imply questioning the very principle of individual freedoms on the Internet. In the medium term it in fact seems implausible to expect an overall

⁴⁸⁵ Luc Boltanski, Eve Chiapello, *Le nouvel esprit du capitalisme*, Gallimard, 1999, p. 547.

⁴⁸⁶ J. P. Barlow, "The economy of ideas: A framework for rethinking patents and copyrights in the digital age (everything you know about intellectual property is wrong)", *Wired*, No. 2.03, March 1994.

⁴⁸⁷ Ulrich Beck, *La Société du risque. Sur la voie d'une modernité*, Flammarion 2008.

⁴⁸⁸ Henri Atlan, *De la fraude, le monde de l'ONAA*, Editions du Seuil, 2010, p. 122.

⁴⁸⁹ Regarding this, it would be useful to ask certain institutions (Interpol) or private organisations (MarkMonitor) about the frequency of resurgence of the deleted sites, which is no doubt high.

⁴⁹⁰ Guillaume Tissier (dir.), CEIS, *Les marchés noirs de la cybercriminalité*, June 2011, p. 66.

⁴⁹¹ Sébastien Darnault, Director of Sales and Marketing for France-Belgium-Luxembourg-Switzerland at MarkMonitor, interviewed by Global Security Mag, MarkMonitor study: *Le piratage sur internet est énorme et un problème complexe*, January 2011.

⁴⁹² Cormac Callanan, Estelle De Marco, Hein Dries-Ziekenheiner, Marco Gercke, *Internet Blocking: Balancing Cybercrime Responses in Democratic Societies*, Open Society Institute Report, 2009.

decrease in the risk of Internet crimes: a study conducted by the Oxford Internet Institute⁴⁹³ concluded that for 38% of experts surveyed, the Internet will never provide a minimal risk of crime and a reasonable degree of privacy, and only 27% of them think that the situation will improve by 2020.

In this context: what law enforcement solutions are there to counter criminal strategies on the Internet?

- Four priorities for more effective law enforcement

Four priorities warrant further consideration to improve the fight against online crime linked to medicine counterfeiting.

The first priority area involves *targeted lobbying*. This lobbying would especially concern middlemen helping to promote online counterfeiting sites and in particular search engines.

Indeed, adequate legal lobbying can be effective: as a result of measures taken by the FDA, in 2010 Yahoo⁴⁹⁴ and Google had to adapt their search engine to retain only accredited online pharmacies (VIPPS - Verified Internet Pharmacy Practice Sites). In September 2010, Google sued several pharmaceutical advertisers who circumvented its new policy and in January 2011 the Californian company tightened its selection criteria once again. On a European or even international scale, pressure on the middlemen can therefore be useful when well argued and relayed effectively by policy. That said, the impact of this legal arsenal against illegal online pharmacies should be put into perspective as, on the Internet, “conventional legislation against illegal online pharmacies is actually less effective than against illegal physical entities”.⁴⁹⁵

A more original type of lobbying could target consumer protection associations or health sector representatives. With “public health” arguments it is possible to convince people of the need to better inform consumers but especially pharmaceutical middlemen (wholesalers, importers) about the risks and trends in online counterfeit medicine distribution.

The second idea is to identify the *strategic hubs* of online counterfeit medicine distribution. This strategy involves having, on a regular basis, a ‘snapshot’ of the most significant illicit trafficking.

According to a recent LegitScript report⁴⁹⁶, while there are 450 accredited companies worldwide for registering domain names, half of illegal online pharmacies, which mostly sell medicines without requiring a prescription, actually obtain their domain name from two companies: Internet.bs and AB Systems. More specifically, at least one-third of illegal online pharmacies use Internet.bs, a relatively small company operating in the Bahamas and that advertises aggressively under the title ‘offshore company’. As for the second operator, AB Systems, it exists solely for illegal online pharmacies to register domain names and advertise.

⁴⁹³ Ian Brown, Oxford Internet Institute, with SCF Associates Ltd, Towards a Future Internet, Interrelation between Technological, Social and Economic Trends, Final Report for DG Information Society and Media, November 2010.

⁴⁹⁴ Pnewswire.com, “NABP Welcomes Yahoo to Pool of Search Engines Requiring VIPPS Accreditation for Internet Pharmacy Advertiser”, PR Newswire US, June 10, 2010.

⁴⁹⁵ European Federation of Pharmaceutical Industries and Association, “Tracking Illegal Internet Pharmacies”, Position Paper Internet Security and Patient Safety, October 26, 2010.

⁴⁹⁶ Legitscript, Internet.bs: A Safe Haven for Drug-Related Cybercrime, March 2012.

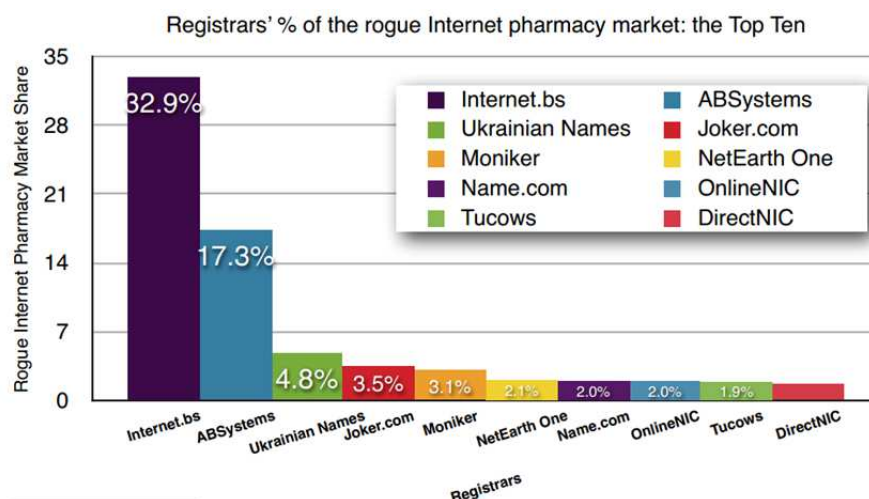


Figure 19: The Top 10 domain names that control illicit pharmacies.
Source of chart: Legitscript, March 2012.

As LegitScript states, ICANN⁴⁹⁷ should have the means to challenge the Internet.bs website's right to register domain names.⁴⁹⁸ Based on this argument, lobbying ICANN would seem highly useful. The idea would be to steer law enforcement *as early as possible* before the risk of counterfeiting, namely by soliciting Internet-related organisations that have a strategic role often misjudged by many stakeholders.

As we discussed earlier⁴⁹⁹, initiatives relating to the results of the main search engines to block access to the most visible counterfeit medicine distribution websites also seems essential.

Computer experts could be used to negotiate better with the major search engines on issues that are highly technical. A growing 'public-private' partnership approach is essential here and LegitScript cooperates with the Center for Safe Internet Pharmacies (CSIP)⁵⁰⁰, a non-profit organisation of leading companies to create a portal with a database with which Internet service providers can monitor and close down illegal websites.

The third idea is indeed to establish leading partnerships with research centres specialising in digital issues. We have been able to identify relevant studies by research centres in California and New York⁵⁰¹. The purpose of such a partnership would be twofold:

- To better understand on a global scale how online counterfeit medicine distribution works and analyse the major trends scientifically and independently. It is important to note here that data from specialised companies

⁴⁹⁷ ICANN is a private US non-profit organisation established in 1998 that in practice issues delegation rights on the sale of domain names to different organisations.

ICANN: Internet Corporation for Assigned Names and Numbers.

⁴⁹⁸ Legitscript, Internet.bs: A Safe Haven for Drug-related Cybercrime, March 2012.

⁴⁹⁹ Nicolas Christin, Nektarios Leontiadis, Tyler Moore, *Measuring and Analyzing Search-Redirection Attacks in the Illicit Online Prescription Drug Trade*, 20th USENIX Security Symposium San Francisco, August 8-12, 2011.

⁵⁰⁰ NABP, Internet Drug Outlet Identification Program. Progress Report for State and Federal Regulators, July 2012, p. 8.

⁵⁰¹ Respectively the Department of Computer Science and Engineering at the University of California, San Diego and The National Center on Addiction and Substance Abuse of Columbia University.

like MarkMonitor and Sophos can sometimes be conflicting: for example, in the ranking of the leading spam-relaying countries, studies⁵⁰² by these two companies conducted at similar dates (summer 2009 and January-March 2010), placed China in first place (MarkMonitor) and fifteenth place (Sophos). It is therefore necessary to regularly provide independent information from the private sector using transparent methods to ensure that such information can be used to help stakeholders with decision-making as it is difficult to incorporate issues that are both industrial and digital on a global scale. The newness of the subject explains this situation in part.

- Secondly, technical solutions with such advanced laboratories could be tested and even replicated on a larger scale. They would no doubt cost less than the work of companies specialised in this field and could facilitate innovative solutions that could help all drug manufacturers affected by counterfeiting. Lastly, it would be useful, in partnership with these research centres, to fully consider the developments in this information society because it is likely that, like Google, new Internet companies will soon disrupt brand and product protection strategies in the pharmaceutical sector.

The fourth priority involves an overview of the criminal issues and paradoxically favours “offline” activities to fight against illegal online distribution. Medicine counterfeiting is “a multifaceted problem that requires a global holistic response”.⁵⁰³ The challenge is to avoid the exhaustion of hunting down every counterfeiter on the Internet but to always involve the ‘real world’ in analyses and operational actions. Indeed, the Internet is just one stream in the distribution of counterfeit medicines and it is essential to identify, for the most extensive distribution networks, at what level there are connections between ‘real distribution’ and ‘online distribution’. On a more theoretical level, more generally one can consider that “an increasing number of activities are born in digital spaces and non-digital spaces”⁵⁰⁴ and stress the importance of an analytical “border zone”⁵⁰⁵ between these two worlds and the concept of ‘interlocking’ to perceive this challenge as “the real and digital have reciprocal effects but do not become hybrid and each world maintains its particularities”.⁵⁰⁶ As Europol has stated, such flexibility “requires investigators to be well aware of both online and offline environments in which criminals operate”.⁵⁰⁷ The analysis of offline trade in relation to online activities is particularly relevant in ‘grey’ zones such as free trade zones or free ports: indeed, according to Ilisa Bernstein⁵⁰⁸, Director of Pharmacy Affairs at the FDA, a number of vendors on the Internet are based in these free trade zones. According to the International Chamber of Commerce⁵⁰⁹, these areas include: Paraguay (Cuidad del Este), the United Arab Emirates, China (Hong Kong, Shanghai, Guangdong), Panama, Taiwan and Mexico (Zona Frontera Norte). Yet little information is available on these strategic “criminogenic interstices” in medicine counterfeiting and the goal would therefore be to better understand what lies in the cracks between the ‘real’ and ‘virtual’ worlds.

⁵⁰² MarkMonitor study, *Brandjacking Index*, summer 2009.

Sophos study conducted January to March 2010. Source: Presswire.com, “Dirty dozen spam-relaying countries revealed by Sophos; China dramatically disappears from list of worse spam-relaying nations for the first time”, *M2 Presswire*, April 28, 2010.

⁵⁰³ Albert I. Wertheimer, Perry G. Wang, *Counterfeit Medicines Volume I: Policy, economics and Countermeasures*, ILM Publications, 2012, p. 106.

⁵⁰⁴ Saskia Sassen, *La globalisation. Une sociologie*, Gallimard, 2009, p. 244.

⁵⁰⁵ On the concept of boundaries see Franck Guarnieri, Eric Przyswa, “Cybercriminalité et contrefaçon : pour une nouvelle analyse des risques et des frontières”, *Murs et frontières, Hermès, No. 63*, 2012.

⁵⁰⁶ Ibidem.

⁵⁰⁷ Europol, Threat Assessment, Internet Facilitated Organised Crime, iOCTA, 2011.

⁵⁰⁸ Walt Bogdanich, “Traffic in fake drugs prospers in network of free trade zones”, *The New York Times*, December 18, 2007.

⁵⁰⁹ International Chamber of Commerce, The international anti-counterfeiting directory, Protecting the world against the plague of counterfeiting, 2008, p. 7.

As we suggested earlier we can also assume that the 'real' trade should be prioritised by law enforcers. Issues related to cybercrime organisations or Google are certainly strategic but perhaps improperly, and often fruitlessly, attract public debate, leaving in the shadows the bigger challenges we have mentioned. Therefore our findings are similar to those of anthropologist Bruno Latour⁵¹⁰ according to whom "the expansion of digital technology has greatly increased the *physical* aspect of the networks: the more the digital environment becomes digital, the more the *physical* dimension overrides the *virtual* in a given activity". This view therefore confirms the dominance of the 'real' world in deciphering the '(cyber)crime-counterfeit medicines' combination, which is also expected to have implications for the priorities in the crackdown on identified 'loopholes'. However, we have also seen that all of these reflections should not bring into question the necessary albeit late adjustments to the development of legitimate online pharmacies and strong awareness campaigns for internet users.

At the end of our analysis of law enforcement aspects we observed that the most relevant initiatives, both in analytical and operational terms, are often the result of individual initiatives (blogger Brian Krebs), semi-private initiatives (Legitscript), academic initiatives (Michigan university, US university centres concerning the Internet) or a few rare institutions with a recent or novel approach (MHRA in Britain). Yet these whistleblowers and innovative structures do not appear to be sufficiently considered as 'models' by many policymakers, who are often solicited by highly visible and better 'positioned' institutional and private organisations. Analytically, it is therefore essential, like the company Legitscript, to have more reports and studies, especially on a European scale, to stringently and independently demonstrate the major risks in the area of (cyber)crime to enhance public debate on these complex issues. However, there is a surprising lack of regular European and Asian research on this subject, most studies being British or American and of good quality. It would therefore be useful in particular to have Chinese, Indian, African, North European and Eastern European feedback as these are strategic areas as far as this problem is concerned.

On an operational level, the creation of a mobile international agency with powers to investigate and arrest, focusing on counterfeit medicines (or health-related products) is a serious option that would be relevant if given the appropriate resources. Regarding the Internet, such an agency could rely on specialised partnerships with academia, which is too often neglected on digital issues or on the European cybercrime agency ENISA⁵¹¹, which is surprisingly not involved in issues of online counterfeiting.

⁵¹⁰ Bruno Latour, "Networks, Societies, Spheres: Reflections of an Actor-network Theorist", Keynote speech for the international seminar on network theory: network multidimensionality in the digital age, Annenberg School for Communication and Journalism Los Angeles, February 19, 2010, p. 802.

⁵¹¹ ENISA, <http://www.enisa.europa.eu/>

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Conclusion

Through this analysis, we have demonstrated that there are obvious ties between ‘criminal organisations’ and ‘medicine counterfeiting’. However, although white-collar crime controls most of the trafficking in developed countries, crime in developing countries such as China appears to be much tougher to define. The most common analytical error is to focus on conventional criminal organisations that appear to be more on the fringes of this problem.

There are obviously grey areas both concerning reality but also the extent of the phenomenon, especially its health impacts. The global environment - and thus the counterfeiting and criminal environment-, has clearly gained in complexity and speed under the influence of globalisation, emerging markets, the Chinese industry and the Internet. In this hypercomplexity, we have seen that in many cases, the ‘real and fake’, licit and illicit “are interlocked in an attempt to divert their distinctive signs. They are interconnected, based on new mechanical switching rituals”.⁵¹²

It is therefore important to decipher these ‘new rituals’ further, particularly those related to ‘criminal networks’. Overpassiveness, especially from institutions supposed to fight against counterfeiting, has benefited criminal organisations that cleverly use loopholes in the international system. Crime involved in medicine counterfeiting leads somewhat to “revenge for the purpose that forces us to consider it”⁵¹³ and should make us question further the available studies.

With such a boomerang effect, is it not appropriate to review our analytical system to “conceive extreme phenomena”?⁵¹⁴ Does deciphering the issues of medicine counterfeiting as effectively as possible in the ‘real’ and ‘virtual’ worlds not imply “being more hyper-real than what is real, more virtual than virtual reality”?⁵¹⁵ Is it not true that the fragmentation of law enforcement intelligence and the fragmentation of international trade doubly benefit counterfeiters, who appear to have increasingly professional agility and speed? In short, like the counterfeiters, surely it is important to dramatically anticipate with a sharp flair for loopholes and what is marginal? Yet, as writer Jean Baudrillard quite rightly stated in his book *The perfect crime* in 1995, “we are now lagging behind events. Although they can sometimes appear to fall behind, they in fact have long since overtaken us. Hence a delayed interpretation, which is merely the retrospective presentation of the unforeseeable event”.⁵¹⁶

This extreme vision of the ‘perfect crime’ should be put into perspective as medicine counterfeiting tends to rely more on loopholes than the mastery of counterfeiting networks that operate as we have described.

Law enforcers (including French customs and certain pharmaceutical company investigative departments) often seem to be working professionally and with determination in a difficult and increasingly complex context.

Certainly the issues are also addressed in the medium and long-term term through international negotiations or based on geopolitical parameters that partly escape health professionals.

But as we have detailed, operational flexibilities also exist in the short term and some expertise is clearly underused. Therefore for the industry it is important not only to better understand the illegal trade of counterfeit drugs by acquiring a more powerful and imaginative *centralised intelligence approach* but also to *question law enforcers* on the meaning of their tasks and to guide politician’s budgetary policies based on pragmatic and flexible choices, calling upon independent and credible whistleblowers if necessary.

⁵¹² Jean Baudrillard, *Le crime parfait*, Galilée, 1995, p. 164.

⁵¹³ Jean Baudrillard, *Mots de passe*, le Livre de Poche, 2000, p. 84.

⁵¹⁴ Jean Baudrillard, *Le crime parfait*, Galilée, 1995, p. 97.

⁵¹⁵ Ibidem.

⁵¹⁶ Jean Baudrillard, *Le crime parfait*, Galilée, 1995, p. 146 -147.

As for cybercrime, one may figuratively wonder whether it is not embodied by “intelligent machines” that sense (...) the dark paths of accidents and disasters?”⁵¹⁷ In this context law enforcement on the Internet seems to be currently surpassed by illegal trade and these automated “intelligent machines” and unless the very logic of the network is challenged, the situation, like the real world, will never be entirely controllable. Paradoxically, the partially new challenges of the Internet are more present in the so-called ‘real’ world or in a ‘real-virtual’ interaction still emerging, than strictly speaking on this “network of networks”.

Although the professionals in the sector still appear somehow to control the overall situation, an unexpected major health scare or a major counterfeiting case in a “high media profile” area (China, Europe, North America, etc.) could shake this balance, particularly through communication channels on the Internet where the overzealous ‘tell-all’ policy may damage certain actors’ sometimes excessive taste for secrecy.

Taking rapid new initiatives that are both strategic and operational is therefore not an empty project. Without such initiatives counterfeit medicines would increasingly be “a hidden object that becomes elusive, paradoxical, ambiguous that infects the subject itself with this ambiguity and its analysis protocol”.⁵¹⁸

And it would therefore benefit criminals of all kinds.

⁵¹⁷ Jean Baudrillard, *Le crime parfait*, Galilée, 1995, p. 65.

⁵¹⁸ Jean Baudrillard, *Le crime parfait*, Galilée, 1995, p. 84.



APPENDICES

Glossary of acronyms

- AFSSAPS: The AFSSAPS became the ANSM on May 1, 2012.
- ANSM: French National Agency for the Safety of Medicinal and Health Products
- CEIS: European Strategic Intelligence Company.
- CJEU: Court of Justice of the European Union.
- CNAC: French National Anti-Counterfeiting Committee.
- CREDOC: Research centre for the study and observation of living conditions.
- DEA: Drug Enforcement Administration.
- EAASM: European Alliance for Access to Safe Medicines.
- ENISA: European Network and Information Security Agency.
- FARC: Fuerzas Armadas Revolucionarias de Colombia.
- FBI: Federal Bureau of Investigation.
- FDA: US Food and Drug Administration.
- ICANN: Internet Corporation for Assigned Names and Numbers.
- ICE: US Immigration and Customs Enforcement.
- IFPMA: International Federation of Pharmaceutical Manufacturer & Associations.
- IMPACT: International Medicines Products Anti-counterfeiting Task force.
- INTERPOL: International Criminal Police Organization.
- IRA: Irish Republican Army.
- IRACM: Institute of Research Against Counterfeit Medicines.
- LEEM: French association of pharmaceutical companies.
- MA: Marketing Authorisation.
- MHRA: Medicines and Healthcare products Regulatory Agency.
- NABP: National Association of Boards of Pharmacy.
- NAFDAC: The National Agency for Food and Drug Administration and Control.
- OCLAESP: French central office for the fight against damage to the environment and public health.
- OECD: Organisation of Economic Cooperation and Development.
- OOS: Out Of Specification.
- PSI: Pharmaceutical Security Institute.
- RBN: Russian Business Network.
- SNDJ: French National Judicial Customs Service.
- TAZ: Temporary Autonomy Zone.
- UDRP: Uniform Domain Name Dispute Resolution Policy.
- UN: United Nations.
- UNICRI: United Nations Interregional Crime and Justice Research Institute.
- UNIFAB: French Association of Manufacturers.
- VIPPS: Verified Internet Pharmacy Practice Sites.
- WAITO: World Anti Illicit Traffic Organization.
- WCO: World Customs Organisation.
- WHO: World Health Organization.
- WIPO: World Intellectual Property Organization.
- WTO: World Trade Organization.

List of interviews (in alphabetical order)

1. Roger Bate, Resident Scholar, American Enterprise Institute, Washington D.C., USA.
2. Stéphane Berlot, Regional Manager France, MarkMonitor, Paris, France.
3. Thierry Bourret, Director General of the National Gendarmerie, OCLAEPS, Arcueil, France.
4. Daniel C. K. Chow, Professor, Moritz College of Law, The Ohio State University, Columbus, USA.
5. Philippe Collier, Chief Editor, Contrefaçon Riposte, Paris, France.
6. Silvain Coué, FSP Mekong, International Technical Expert, Advisor to the Commissioner General of the Cambodian National Police, Cambodia.
7. Gregory Crabb, Inspector In Charge, Revenue, Product and Global Security at U.S. Postal Inspection Service, Washington D.C., USA.
8. Michele Forzley, Global Public Health Lawyer & Professor Widener School of Law, Silver Spring, USA.
9. Thomas Gayet, Director Cert-Lexsi, Bagnolet, France.
10. Patrick Haeyaert, Head of Information Management Department, Corporate Economic Security, Sanofi, Paris, France.
11. Mike Jones, F.I. Adviser, MHRA, London, UK.
12. Tom Kubic, President and CEO, PSI, Washington D.C., USA.
13. Jean-Luc Moreau, Global Head Product Security, Novartis, Basel, Switzerland.
14. Doug Moyer, Adjunct Instructor, Program in Public Health, College of Human Medicine, Michigan State University, USA.
15. Jérôme Pierrat, Journalist, Paris, France.
16. Philippe Van Eeckhout, Chairman, Contratak, Paris, France.
17. Chris Vansteenkiste, Project Manager IPR Crime Unit, Europol, The Hague, Netherlands.
18. Simeon Wilson, Director Global Security, Astra Zeneca, London, UK.

Certain interviewees preferred not to be named.

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**International Institute of Research
Against Counterfeit Medicines**

10 avenue Franklin Roosevelt
75008 Paris
France

info@iracm.com
+33 1 69 74 58 11

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